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FED - C0000 - INITIAL COMMENTS

Title INITIAL COMMENTS

CFR

Type Memo Tag

Regulation Definition	Interpretive Guideline

FED - C0150 - COMPLIANCE WITH FEDERAL, STATE, & LOCAL LAWS

Title COMPLIANCE WITH FEDERAL, STATE, & LOCAL LAWS
CFR 485.608

Type Condition

Regulation Definition	Interpretive Guideline
The CAH and its staff are in compliance with applicable Federal, State and local laws and regulations.	Failure of the CAH to meet a Federal, State or local law may only be cited when the Federal, State or local authority having jurisdiction has made both a determination of noncompliance and has taken a final adverse action as a result. Refer or report suspected violations to the appropriate Federal, State, or local agency.

FED - C0151 - COMPLIANCE WITH FEDERAL LAWS & REGULATIONS

Title COMPLIANCE WITH FEDERAL LAWS & REGULATIONS
CFR 485.608(a)

Type Standard

Regulation Definition	Interpretive Guideline
Compliance with Federal laws and regulations. The CAH is in compliance with applicable Federal laws and regulations related to the health and safety of patients.	Interview the CEO, or appropriate individual, to determine whether the CAH is in compliance with Federal laws related to patient health and safety. For example, if the CAH has been convicted of violating a Federal law such as denying people with disabilities access to care, verify that satisfactory corrections have been made to bring the CAH

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into compliance with that law.

Refer noted noncompliance with Federal laws and regulations to the appropriate agency having jurisdiction (e.g., OSHA for accessibility issues, blood borne pathogens, universal precautions, TB control; EPA for hazardous chemical and waste issues, etc.)

For Medicare beneficiaries there are requirements, in addition to those found in the CoPs for CAHs, at 42 CFR 405.1205(b), which requires that hospitals and CAHs provide each Medicare beneficiary who is an inpatient a standardized notice, the Important Message from Medicare (IM), within two days of their admission. IMs are to be signed and dated by the patient when it is delivered to the beneficiary at or near admission. In addition, the rule at 42 CFR 405.1205(b)(3) requires that hospitals and CAHs present a copy of the IM to beneficiaries as far as possible in advance of their discharge, but not more than two calendar days before discharge. In the case of a short inpatient stay, however, where delivery of the IM is within two calendar days of the date of discharge, the second delivery of the IM is not required.

42 CFR 489.27(b) requires hospitals and CAHs to demonstrate compliance with this requirement, cross-referencing the requirements at 42 CFR 405.1205. Surveyors must verify that the hospital/CAH has appropriate policies and procedures in place to ensure that Medicare beneficiaries receive timely notice of their inpatient rights at admission, and if applicable, upon discharge. In addition, surveyors must review selected Medicare patient records to confirm that the records contain documentation verifying timely delivery of the IM, including, where applicable, delivery of a follow-up copy of the IM. Surveyors may also interview hospital/CAH staff to assess their knowledge and understanding of the IM delivery requirements, including the hospital's/CAH s process for delivering the IM and obtaining signature from the patient. Surveyors may also interview patients to verify that the hospital/CAH is providing Medicare beneficiaries with the IM in compliance with the regulatory requirements.

FED - C0152 - COMPLIANCE WITH STATE & LOCAL LAWS

Title COMPLIANCE WITH STATE & LOCAL LAWS

CFR 485.608(b)

Type Standard

Regulation Definition

All patient care services are furnished in accordance with applicable State and local laws and regulations.

Interpretive Guideline

There are wide variations in the States' practice acts relative to the extent to which MD/DOs may delegate responsibilities to nurse practitioners, clinical nurse specialists, and physician assistants. Some states have updated their practice acts to include definitions and specific references to permitted/prohibited activities, supervision/guidance required by a MD/DO, and local situations in which nurse practitioners, clinical nurse

specialists, and physician assistants may function.

Procedures:
Prior to going on the survey, determine what professional specialists provide patient care services at the CAH and review State practice act requirements.

FED - C0153 - LICENSURE OF CAH

Title LICENSURE OF CAH

CFR 485.608(c)

Type Standard

Regulation Definition	Interpretive Guideline
The CAH is licensed in accordance with applicable Federal, State and local laws and regulations.	Survey Procedures Prior to the survey, determine whether the CAH is subject to licensure requirements and verify that the licensing agency has approved the CAH as meeting the standards for licensure as set forth by the agency of the State or locality responsible for licensing CAHs.

FED - C0154 - LICENSURE/CERTIFICATION/REGISTRATION

Title LICENSURE/CERTIFICATION/REGISTRATION

CFR 485.608(d)

Type Standard

Regulation Definition	Interpretive Guideline
Staff of the CAH are licensed, certified, or registered in accordance with applicable Federal, State, and local laws and regulations.	All staff required by the State to be licensed must possess a current license. The CAH must ensure that these personnel are in compliance with the State's licensure laws. The laws requiring licensure vary from state to state. Examples of healthcare professionals that a state may require to be licensed could include: nurses, MD/DOs, physician assistants, dietitians, x-ray technologists, dentists, physical therapists, occupational therapists, respiratory technicians and facility administrators. All CAH staff must meet all applicable standards required by State or local law for CAH personnel. This would include at a minimum: o Certification requirements;

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o Minimum qualifications; and
o Training/education requirements.

Survey Procedures
o Verify for those personnel required to be licensed by the State, that the CAH has established, and follows, procedures for determining that personnel providing patient care services are properly licensed.
o Check a sample of personnel files to verify that licensure information is up to date. Verify that appropriate categories of staff and personnel are licensed in accordance with State requirements. Verify state licensure compliance of the direct care personnel, as well as administrators and supervisory personnel, and any contracted personnel.
o Verify that there are procedures in place to guarantee licensure of employees working at the CAH under contract or agreement.
o Review CAH policies regarding certification, licensure, and registration of personnel. Are the CAH policies compliant with State and local laws? Are the personnel in compliance with CAH policy?

FED - C0160 - STATUS AND LOCATION

Title STATUS AND LOCATION

CFR 485.610

Type Condition

Regulation Definition	Interpretive Guideline
Status and Location	This COP only applies to initial surveys unless the facility relocates. If the CAH moves the location of the CAH to another location, the status and relocation must be reassessed by the State agency and CMS on a case-by-case basis.

FED - C0161 - STATUS

Title STATUS

CFR 485.610(a)

Type Standard

Regulation Definition	Interpretive Guideline
Status. The facility is --(1)a currently participating hospital that meets all conditions of participation set forth in this	Confirm that a CAH meets the basic status requirement prior to scheduling the survey. The appropriate RO will re-verify the status requirement prior to approving a CAH for Medicare certification.

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subpart; (2) a recently closed facility, provided that the facility -(i) was a hospital that ceased operations on or after the date that is 10 years before November 29, 1999; and (ii)meets the criteria for designation under this subpart as of the effective date of its designation; or (3) a health clinic or a health center (as defined by the State) that -(i) is licensed by the State as a health clinic or a health center; (ii) was a hospital that was downsized to a health clinic or a health center; and (iii) as of the effective date of its designation, meets the criteria for designation set forth in this subpart.

FED - C0162 - LOCATION IN A RURAL AREA OR TRTMNT AS RURAL

Title LOCATION IN A RURAL AREA OR TRTMNT AS RURAL
CFR 485.610(b)

Type Standard

Regulation Definition

The CAH meets the requirements of paragraph (b)(1), (b)(2) or (b)(3) of this section.

(1) The CAH meets the following requirements:
(i) The CAH is located outside any area that is a Metropolitan Statistical Area, as defined by the Office of Management and Budget, or that has been recognized as urban under §412.64(b), excluding paragraph (b)(3) of this chapter;
(ii) The CAH has not been classified as an urban hospital for purposes of the standardized payment amount by CMS or the Medicare Geographic Classification Review Board under §412.230(e) of this chapter, and is not among a group of hospitals that have been re-designated to an adjacent urban area under §412.232 of this chapter.

(2) The CAH is located within a Metropolitan Statistical Area, as defined by the Office of Management and Budget, but is being treated as being located in a rural area in accordance

Interpretive Guideline

"Urban area" means (effective October 1, 2004) a Metropolitan Statistical Area (MSA), as defined by the Office of Management and Budget; or a New England county deemed to be an urban area (as specified under 412.64) to include the following New England Counties: Litchfield County, Connecticut; York County, Maine; Merrimack County, New Hampshire; Newport County, Rhode Island; and Fagadahoe County, Maine.

A "Metropolitan CAH" is a CAH that is located within a MSA but is being treated as being located in a rural area. A hospital that wishes to convert to a CAH, and is located in an urban area, must be reclassified as a rural CAH by submitting an application, prior to conversion, to the regional office of CMS. Prior to conversion, the facility must meet one of the following criteria and explain how they meet the criteria for reclassification as rural, including data and documentation necessary to support the request, in the application for reclassification. Reference 42 CFR §412.103.
o The facility is located in a rural census tract of an MSA as determined under the most recent version of the Goldsmith Modification; or
o The facility is located in an area designated as a rural area by any law or regulation of the State in which it is located; or
o The facility is designated as a rural CAH by State law or regulation; or
o The facility would qualify as a rural referral center or as a sole community hospital.

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with §412.103 of this chapter.

(3) Effective only for October 1, 2004 through September 30, 2006, the CAH does not meet the location requirements in either paragraph (b)(1) or (b)(2) of this section and is located in a county that, in FY 2004, was not part of a Metropolitan Statistical Area as defined by the Office of Management and Budget but as of FY 2005 was included as part of such an MSA as a result of the most recent census data and implementation of the new MSA definitions announced by OMB on June 6, 2003.

Survey Procedures
Determine that a CAH meets the basic location requirement prior to scheduling the survey. The appropriate RO will re-verify the location requirement prior to approving a CAH for Medicare certification.

FED - C0165 - LOCATION RELATIVE TO OTHER FACILITIES

Title LOCATION RELATIVE TO OTHER FACILITIES

CFR 485.610(c)

Type Standard

Regulation Definition

The CAH is located more than a 35-mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital or another CAH, or before January 1, 2006, the CAH is certified by the State as being a necessary provider of health care services to residents in the area. A CAH that is designated as a necessary provider on or before December 31, 2005, will maintain its necessary provider designation after January 1, 2006.

Interpretive Guideline

A CAH that can document that it was designated by a State as a necessary provider CAH prior to January 1, 2006 does not have to meet the location relative to other facilities standard at §485.610(c). As of January 1, 2006 States do not have the authority to designate any new necessary provider CAHs. Necessary provider CAHs that were designated prior to that date are grandfathered by statue, subject to certain conditions if they relocate (see the discussion related to §485.610(d). ROs and SAs should have the documentation related to a CAH ' s original necessary provider designation documents.
For applicants seeking a new CAH provider agreement, or for CAHs that seek to relocate and do not have a grandfathered necessary provider designation, ROs will review the application and make the determination whether it satisfies the CAH location relative to other facilities standard at §485.610(c), using the guidance found in 2256A of the State Operations Manual. At the conclusion of its review, the RO will notify the SA of its determination.

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FED - C0166 - RELOCATION OF CAHS W NECESSARY PRVDR DSGNTN

Title RELOCATION OF CAHS W NECESSARY PRVDR DSGNTN
CFR 485.610(c)

Type Standard

Regulation Definition

A CAH that has a necessary provider designation from the State that was in effect prior to January 1, 2006, and relocates its facility after January 1, 2006, can continue to meet the location requirement of paragraph (c) of this section based on the necessary provider designation only if the relocated facility meets the requirements as specified in paragraph (d)(1) of this section.

(1) If a necessary provider CAH relocates its facility and begins providing services in a new location, the CAH can continue to meet the location requirement of paragraph (c) of this section based on the necessary provider designation only if the CAH in its new location--

(i) Serves at least 75 percent of the same service area that it served prior to its relocation;

(ii) Provides at least 75 percent of the same services that it provided prior to the relocation; and

(iii) Is staffed by 75 percent of the same staff (including medical staff, contracted staff, and employees) that were on staff at the original location.

(2) If a CAH that has been designated as a necessary provider by the State begins providing services at another location after January 1, 2006, and does not meet the requirements in paragraph (d)(1) of this section, the action will be considered a cessation of business as described in §489.52(b)(3).

Compliance with hospital requirements at the time of

Interpretive Guideline

Renovation or expansion of a CAH's existing building or addition of building(s) on the existing main campus of the CAH is not considered a relocation. However, as discussed in the adoption of this regulation (70 FR 47472), all newly-constructed, necessary provider CAH facilities, including entirely new replacement facilities constructed on the same site as the existing CAH main campus, are considered relocated facilities. The determination of whether or not CAHs with a necessary provider designation have met the requirements of §485.610(d) will be made by the RO, generally prior to an SA or accreditation survey. The RO will utilize the evaluation criteria set forth in SOM Section 2256F to make this determination. At the conclusion of its review, the RO will notify the SA of its results.

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application. Except for recently closed facilities as described in §485.610(a)(2), or health clinics or health centers as described in §485.610(a)(3), the facility is a hospital that has a provider agreement to participate in the Medicare program as a hospital at the time the hospital applies for designation as a CAH.

FED - C0167 - STATUS AND LOCATION

Title STATUS AND LOCATION

CFR 485.610(e)

Type Standard

Regulation Definition

Standard: Off-campus and co-location requirements for CAHs. A CAH may continue to meet the location requirement of paragraph (c) of this section based only if the CAH meets the following:

(1) If a CAH with a necessary provider designation is co-located (that is, it shares a campus, as defined in §413.65(a)(2) of this chapter, with another hospital or CAH), the necessary provider CAH can continue to meet the location requirement of paragraph (c) of this section only if the co-location arrangement was in effect before January 1, 2008, and the type and scope of services offered by the facility co-located with the necessary provider CAH do not change. A change of ownership of any of the facilities with a co-location arrangement that was in effect before January 1, 2008, will not be considered to be a new co-location arrangement.

(2) If a CAH or a necessary provider CAH operates an off-campus provider based location, excluding an RHC as defined in §405.2401(b) of this chapter, but including a department or remote location, as defined in §413.65(a)(2) of this chapter, or an off-campus distinct part psychiatric or

Interpretive Guideline

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rehabilitation unit, as defined in §485.647, that was created or acquired by the CAH on or after January 1, 2008, the CAH can continue to meet the location requirement of paragraph (c) of this section only if the off-campus provider based location or off-campus distinct part unit is located more than a 35 mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15 mile drive) from a hospital or another CAH.

(3) If either a CAH or a CAH that has been designated as a necessary provider by the State does not meet the requirements in paragraph (e)(1) of this section, by co-locating with another hospital or CAH on after January 1, 2008, or creates or acquires an off-campus provider-based location or off-campus distinct part unit on or after January 1, 2008, that does not meet the requirements in paragraph (e)(2) of this section, the CAH's provider agreement will be subject to termination in accordance with the provisions of §489.53(a)(3) of this subchapter, unless the CAH terminates the off-campus arrangement or the co-location arrangement or both.

FED - C0170 - COMPLIANCE WITH HOSPITAL REQUIREMENTS

Title COMPLIANCE WITH HOSPITAL REQUIREMENTS
CFR 485.612

Type Condition

Regulation Definition

Compliance with hospital requirements at the time of application. Except for recently closed facilities as described in §485.610(a)(2), or health clinics or health centers as described in §485.610(a)(3), the facility is a hospital that has a provider agreement to participate in the Medicare program as a hospital at the time the hospital applies for designation as a CAH.

Interpretive Guideline

This CoP only applies to initial surveys. All facilities that apply to become a CAH under one of the following situations are surveyed using the CAH CoP to determine compliance.
o A currently operating hospital in compliance who is converting to a CAH; or
o A re-opened hospital converting to a CAH; or
o A hospital that down-sized to become a clinic and wishes to convert to a CAH.

If a facility has never been a Medicare participating hospital and wishes to be a CAH, the facility is a new provider to

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Medicare and must first meet the certification as a hospital and then put in a change of status request to be a CAH. In these cases, the facility must be surveyed twice. They must be initially surveyed using the hospital CoP and, when the change request is received, they must be surveyed again using the CAH CoP. In addition, these facilities are to be treated as new providers to Medicare necessitating completion of an application package as a new Medicare provider.

FED - C0190 - AGREEMENTS

Title AGREEMENTS

CFR 485.616

Type Condition

Regulation Definition	Interpretive Guideline
Agreements	The CAH must ensure that the agreement requirements are met.

FED - C0191 - AGREEMENTS WITH NETWORK HOSPITALS

Title AGREEMENTS WITH NETWORK HOSPITALS

CFR 485.616(a)

Type Standard

Regulation Definition	Interpretive Guideline
In the case of a CAH that is a member of a rural health network as defined in §485.603 of this chapter, the CAH has in effect an agreement with at least one hospital that is a member of the network for - (1) patient referral and transfer.	Section 485.603 defines a rural health network as an organization that includes at least one hospital that the State has designated or plans to designate as a CAH, and at least one hospital that furnishes acute care (hospital) services. All Medicare-certified CAHs are members of a rural health network in the State and are subject to the CoP §485.616.

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FED - C0193 - AGREEMENTS WITH NETWORK HOSPITALS

Title AGREEMENTS WITH NETWORK HOSPITALS

CFR 485.616(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
[...the CAH has in effect an agreement with at least one hospital that is a member of the network for -]	Survey Procedures o If the CAH is a member of a rural health network having a communications system, ask to see the agreement. o How does the CAH participate with other hospitals and facilities in the network communications system? o Is a communications log kept at the facility? o Ask staff if there have been difficulties in contacting network members. If so, ask how the CAH deals with communication delays. o How does the network's communications system compare with any available communications equipment in the CAH?
(2) the development and use of communication systems of the network, including the network's system for the electronic sharing of patient data, and telemetry and medical records, if the network has in operation such a system;	

FED - C0194 - AGREEMENTS WITH NETWORK HOSPITALS

Title AGREEMENTS WITH NETWORK HOSPITALS

CFR 485.616(a)(3)

Type Standard

Regulation Definition	Interpretive Guideline
[...the CAH has in effect an agreement with at least one hospital that is a member of the network for --]	Survey Procedures Review any written agreements including any local EMS service.
(3) the provision of emergency and nonemergency transportation between the facility and the hospital.	

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FED - C0195 - AGREEMENTS - CREDENTIALING & QA

Title AGREEMENTS - CREDENTIALING & QA

CFR 485.616(b)

Type Standard

Regulation Definition	Interpretive Guideline
Each CAH that is a member of a rural health network shall have an agreement with respect to credentialing and quality assurance with at least - (1) one hospital that is a member of the network; (2) one QIO or equivalent entity; or (3) one other appropriate and qualified entity identified in the State rural health care plan.	Other qualified entities could include another CAH or any licensed firms, businesses, or agencies that provide credentialing and QA services. The location for these other qualified entities is not limited to local entities or confined to the State borders. The State determines who is a qualified entity for credentialing and quality assurance under §485.616(b)(3). Agreements for QA must include medical record review as part of the determination of the quality and medical necessity of medical care at the CAH. These reviews must include both inpatients and outpatients, and must be inclusive of all services provided at the CAH such as swing-bed, distinct part units, and satellite locations. Survey Procedures o Review any agreements related to credentialing or quality assurance to determine the level of assistance to be provided and the responsibilities of the CAH. o Review policies and procedures to determine how information is to be obtained, utilized, and how confidentiality of information will be maintained.

FED - C0200 - EMERGENCY SERVICES

Title EMERGENCY SERVICES

CFR 485.618

Type Condition

Regulation Definition	Interpretive Guideline
The CAH provides emergency care necessary to meet the needs of its inpatients and outpatients.	The CAH's emergency services must be under the direction of a qualified member of the CAH's medical staff. The CAH's medical staff establishes criteria for the qualifications for the director of the CAH's emergency services in accordance with State law and acceptable standards of practice.

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The CAH's medical staff must establish policies and procedures governing the medical care provided in the emergency services or emergency department. Emergency services or emergency department policies must be current and revised as necessary based on the ongoing monitoring conducted by the medical staff and the emergency service or department QA activities. The CAH's emergency services must be integrated into the CAH-wide QA program.

The medical staff must establish criteria, in accordance with State law, regulations, and guidelines, delineating the qualifications a medical staff member must possess in order to be granted privileges for the provision of emergency care services. Qualifications include necessary education, experience and specialized training, consistent with State law and acceptable standards of practice.

The CAH must staff the emergency department with the appropriate numbers and types of professionals and other staff who possess the skills, education, certifications, specialized training and experience in emergency care to meet the written emergency procedures and needs anticipated by the facility. There must be sufficient medical and nursing personnel to respond to the emergency medical needs and care of the patient population being served.

The CAH must determine the categories and numbers of MD/DOs, specialists, RNs, EMTs, and emergency department support staff the CAH needs to meet its anticipated emergency needs. The medical staff must establish criteria, in accordance with State law and regulations and acceptable standards of practice delineating the qualifications required for each category of emergency services staff (e.g., emergency physicians, specialist MD/DO, RNs, EMTs, mid-level practitioners, etc.).

The CAH must conduct ongoing assessments of its emergency needs in order to anticipate the policies, procedures, staffing, training, and other resources that may be needed to address likely demands.

Emergency care necessary to meet the needs of its inpatients and outpatients would include the provision of respiratory services as needed by the CAH's emergency patients. When respiratory services are provided those services must be provided in accordance with acceptable standards of practice. The scope of diagnostic and/or therapeutic respiratory services offered by the CAH should be defined in writing, and approved by the medical staff.

The CAH must provide the appropriate equipment and qualified personnel necessary to furnish all services offered in a safe manner in accordance with acceptable standards of practice.

There should be written policies for the delivery of any services provided. The policies and procedures must be developed and approved by the medical staff and include the participation of any mid-level practitioners working in the ED. The written policies should address the following services, as appropriate:

o Each type of service provided by the CAH;
o The qualifications, including job title, licensure requirements, education, training and experience of personnel authorized to perform each type of respiratory care service and whether they may perform it without supervision;
o Equipment assembly and operation;
o Safety practices, including infection control measures;
o Handling, storage, and dispensing of therapeutic gases;
o Cardiopulmonary resuscitation;
o Procedures to follow in the advent of adverse reactions to treatments or interventions;
o Pulmonary function testing;
o Therapeutic percussion and vibration;
o Bronchopulmonary drainage;
o Mechanical ventilatory and oxygenation support;
o Aerosol, humidification, and therapeutic gas administration;
o Administration of medications; and
o Procedures for obtaining and analyzing blood samples (arterial blood gases).

Survey Procedures
o Verify that emergency services are organized under the direction of a qualified member of the medical staff.
o Verify that procedures and policies for emergency medical services (including triage of patients and any respiratory services provided) are established, evaluated, and updated on an ongoing basis.
o Verify that there are sufficient medical and nursing personnel qualified in the needs anticipated by the facility and that there are specific assigned duties for emergency care.
o Review any policies and procedures for emergency services in the CAH. What evidence indicates that the CAH is capable of providing necessary emergency care for its inpatients and outpatients?
o Review a sample of patient records for patients treated in the emergency services department to see if the CAH followed its own policies and procedures.
o Verify that emergency services are provided in accordance with acceptable standards of practice.
o Interview staff to determine that they are knowledgeable, within their own level of participation in emergency care including:
- Parenteral administration of electrolytes, fluids, blood and blood components;
- Care and management of injuries to extremities and central nervous system;
- Prevention of contamination and cross infection; and
- Provision of emergency respiratory services.
o Determine if the CAH provides any degree of respiratory care services and that the type and amount of respiratory care provided meets the needs of the patients and is delivered in accordance with acceptable standards of practice.

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o Review the CAH policies and procedures to verify that the scope of the diagnostic and/or therapeutic respiratory care services provided is defined in writing and approved by the medical staff.
o Review staffing schedules to determine that the number and type of staff available is appropriate to the volume and types of treatments furnished.
o If blood gases or other laboratory tests are performed as part of the delivery of respiratory services, verify that there is a current CLIA certificate.

FED - C0201 - AVAILABILITY

Title AVAILABILITY

CFR 485.618(a)

Type Standard

Regulation Definition	Interpretive Guideline
Emergency services are available on a 24-hours a day basis.	The phrase "the CAH emergency services are available on a 24-hours a day basis" does not mean that the CAH must remain open 24 hours a day when it does not have inpatients (including swing-bed patients). A CAH that does not have inpatients may close with no staff present, provided that it has an effective system in place to meet the requirement. The system must ensure that a practitioner with training and experience in emergency care is on call and immediately available by telephone or radio, and available on site within 30 minutes, (or 1 hour in certain frontier areas), 24 hours a day. Survey Procedures Ascertain by record review of patients admitted through the emergency department, interviews with staff, patients, and families, and/or observations that ED services were made available to patients presenting on a 24-hour a day basis. How does the CAH ensure that emergency services are made available on a 24-hour a day basis?

FED - C0202 - EQUIPMENT, SUPPLIES AND MEDICATION

Title EQUIPMENT, SUPPLIES AND MEDICATION

CFR 485.618(b)

Type Standard

Regulation Definition	Interpretive Guideline
Equipment, supplies and medication used in treating	In addition to these items, the CAH must maintain the types, quality and numbers of supplies, drugs and biologicals,

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emergency cases are kept at the CAH and are readily available for treating emergency cases. The items available must include the following:

blood and blood products, and equipment required by State and local law and in accordance with accepted standards of practice.

Survey Procedures
o How does the CAH ensure that the required equipment, supplies and medications are always readily available in the CAH?
o Interview staff and tour the ER to ascertain compliance and ability to provide emergency services.

FED - C0203 - EQUIPMENT, SUPPLIES & MEDICATION

Title EQUIPMENT, SUPPLIES & MEDICATION

CFR 485.618(b)(1)

Type Standard

Regulation Definition

[The items available must include the following:]

(1) Drugs and biologicals commonly used in life-saving procedures, including analgesics, local anesthetics, antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids, antiarrythmics, cardiac glycosides, antihypertensives, diuretics, and electrolytes and replacement solutions.

Interpretive Guideline

Survey Procedures
o How does the CAH ensure that staff knows where drugs and biologicals are kept?
o How is the inventory maintained?
o Who is responsible for monitoring drugs and biologicals?
o How are drugs and biologicals replaced?

FED - C0204 - EQUIPMENT, SUPPLIES & MEDICATION

Title EQUIPMENT, SUPPLIES & MEDICATION

CFR 485.618(b)(2)

Type Standard

Regulation Definition

[The items available must include the following:]

(2) Equipment and supplies commonly used in life saving procedures, including airways, endotracheal tubes, ambu

Interpretive Guideline

Survey Procedures
o How does the CAH ensure that required equipment and supplies are readily available to staff?
o How does the CAH ensure that staff knows where emergency equipment and supplies are kept?
o How is the supply inventory maintained?

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bag/valve/mask, oxygen, tourniquets, immobilization devices, nasogastric tubes, splints, IV therapy supplies, suction machine, defibrillator, cardiac monitor, chest tubes, and indwelling urinary catheters.

o Who is responsible for monitoring supplies?
o How are supplies replaced?
o When was the last time emergency supplies were used?
o Is there an equipment maintenance schedule (e.g., for the defibrillator)?
o Ask staff if equipment has ever failed to work when needed.
o Examine sterilized equipment (e.g., tracheostomy sets) for expiration dates when applicable.
o Examine the oxygen supply system to determine functional capabilities.
o Check the force of the vacuum (suction) equipment to see that it is in operating condition.

FED - C0205 - BLOOD AND BLOOD PRODUCTS

Title BLOOD AND BLOOD PRODUCTS

CFR 485.618(c)(1)

Type Standard

Regulation Definition

The facility provides, either directly or under arrangement, the following:

(1) services for the procurement, safekeeping, and transfusion of blood, including the availability of blood products needed for emergencies on a 24-hours a day basis

Interpretive Guideline

This requirement can be met at a CAH by providing blood or blood products on an emergency basis at the CAH, either directly or through arrangement, if that is what the patient's condition requires. There is no requirement in the regulation for a CAH to store blood on site, although it may choose to do so. In some cases, it may be more practical to transport a patient to the source of the blood supply than to bring blood to the patient at the CAH. A facility that has the capability of providing blood services on site would be in compliance even if, in virtually all cases, the patients were actually taken to the blood rather than vice versa.

A CAH that performs CLIA tests on blood on-site must have a CLIA certificate and is subject to survey under CLIA. A CAH that is only storing blood for transfusion and refers all related testing out to another laboratory, is not performing testing as defined by CLIA. However, under this regulation, the CAH must ensure that blood is appropriately stored to prevent deterioration, including documenting refrigerator temperatures. The provision of blood services between the CAH and the testing laboratory should be reflected in the written agreement or arrangement between the two. Also, if the CAH is collecting blood, it must register with the Food and Drug Administration.

"Availability" in this context, means that the blood and blood products must be accessible to CAH staff in time to effectively treat emergency patients at the CAH. In order to comply with this requirement, a CAH must demonstrate that it has the capability (i.e., an effective system is in place regardless of whether, in actual practice, it has been utilized) of making blood products available to its emergency patients 24 hours a day.

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If a CAH performs type and compatibility testing it must have the necessary equipment, (i.e., serofuge and heat block), as well as typing and cross matching reagents, some of which have a 30-day expiration date. Another way for a CAH to meet this requirement would be to properly store 4 units of O negative packed red blood cells (the universal donor type) for availability at all times for emergencies only. Those CAHs that choose to store O negative packed red blood cells for emergency release of uncross matched blood will require a release form to be signed by a doctor, prior to transfusion, acknowledging that the blood has not been cross matched for the patient. Facilities that elect to store units of O negative packed red blood cells should be able to demonstrate that they have an arrangement (e.g., with the Red Cross or other similar product provider) for the provision of fresh units of O negative packed red blood cells.

FED - C0206 - BLOOD AND BLOOD PRODUCTS

Title BLOOD AND BLOOD PRODUCTS

CFR 485.618(c)(2)

Type Standard

Regulation Definition

[The facility provides, either directly or under arrangements, the following:

(2) blood storage facilities that meet the requirements of 42 CFR Part 493, Subpart K, and are under the control and supervision of a pathologist or other qualified doctor of medicine or osteopathy. If blood banking services are provided under an arrangement, the arrangement is approved by the facility's medical staff and by the persons directly responsible for the operation of the facility.

Interpretive Guideline

Survey Procedures
o If blood banking services are provided on site, what evidence shows that the blood facility is under the control and supervision of a pathologist or other qualified MD/DO?
o For blood banking services provided under arrangement, what evidence shows that the CAH medical staff and the person responsible for CAH operations have approved the arrangement?

FED - C0207 - PERSONNEL

Title PERSONNEL

CFR 485.618(d)

Type Standard

Aspen Federal Regulation Set: C 04.02 CRITICAL ACCESS HOSPITALS

Regulation Definition

(1) Except as specified in paragraph (d)(3) of this section, there must be a doctor of medicine or osteopathy, a physician assistant, a nurse practitioner, or a clinical nurse specialist, with training or experience in emergency care, on call and immediately available by telephone or radio contact, and available on site within the following timeframes:
(i) Within 30 minutes, on a 24-hour a day basis, if the CAH is located in an area other than an area described in paragraph (d)(1)(ii) of this section; or
(ii) within 60 minutes, on a 24-hour a day basis, if all of the following requirements are met:
(A) The CAH is located in an area designated as a frontier area (that is, an area with fewer than six residents per square mile based on the latest population data published by the Bureau of the Census) or in an area that meets criteria for a remote location adopted by the State in its rural health care plan, and approved by CMS, under section 1820(b) of the Act.
(B) The State has determined, under criteria in its rural health care plan, that allowing an emergency response time longer than 30 minutes is the only feasible method of providing emergency care to residents of the area served by the CAH.
(C) The State maintains documentation showing that the response time of up to 60 minutes at a particular CAH it designates is justified because other available alternatives would increase the time needed to stabilize a patient in an emergency.

(2) A registered nurse with training and experience in emergency care can be utilized to conduct specific medical screening examinations only if
(i) The registered nurse is on site and immediately available at the CAH when a patient requires medical care; and
(ii) The nature of the patient ' s request for medical care is within the scope of practice of a registered nurse and

Interpretive Guideline

When State laws are more stringent and require more stringent staffing or expanded operational hours, the CAH must staff its emergency department in accordance with state laws. For example, if State law requires the CAH emergency department be open and be staffed with a MD/DO 24/7 then the CAH must comply.

Survey Procedures
o Review on-call schedules to determine how the CAH ensures that a qualified staff member is on call 24 hours a day and available on site at the CAH within 30 minutes, or 60 minutes in certain frontier areas.
o Interview staff to determine how the CAH staff knows who is on call.
o What documentation demonstrates that a MD/DO, nurse practitioner, physician assistant, or registered nurse, (as allowed under (d)(2)) with emergency training or experience, has been on call and available on site at the CAH within 30 or 60 minutes, as appropriate?

consistent with applicable State laws and the CAH's bylaws or rules and regulations.

(3)A registered nurse satisfies the personnel requirement specified in paragraph (d)(1) of this section for a temporary period if --
(i) The CAH has no greater than 10 beds;
(ii) The CAH is located in an area designated as a frontier area or remote location as described in paragraph (d)(1)(ii)(A) of this section;
(iii) The State in which the CAH is located submits a letter to CMS signed by the Governor,
following consultation on the issue of using RNs on a temporary basis as part of their State rural health care plan with the State Boards of Medicine and Nursing, and in accordance with State law, requesting that a registered nurse with training and experience in emergency care be included in the list of personnel specified in paragraph (d)(1) of this section. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of emergency services in the States. The letter from the Governor must also describe the circumstances and duration of the temporary request to include the registered nurses on the list of personnel specified in paragraph (d)(1) of this section.
(iv) Once a Governor submits a letter, as specified in paragraph (d)(3)(iii) of this section, a CAH must submit documentation to the State survey agency demonstrating that it has been unable, due to the shortage of such personnel in the area, to provide adequate coverage as specified in this paragraph (d).

(4)The request, as specified in paragraph (d)(3)(iii) of this section, and the withdrawal of the request, may be submitted to us at any time, and are effective upon submission.

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FED - C0209 - COORDINATION WITH EMERGENCY RESPONSE SYSTEMS

Title COORDINATION WITH EMERGENCY RESPONSE SYSTEMS

CFR 485.618(e)

Type Standard

Regulation Definition	Interpretive Guideline
The CAH must, in coordination with emergency response systems in the area, establish procedures under which a doctor of medicine or osteopathy is immediately available by telephone or radio contact on a 24-hours a day basis to receive emergency calls, provide information on treatment of emergency patients, and refer patients to the CAH or other appropriate locations for treatment.	The CAH, not the local ambulance service, is responsible for ensuring that an effective procedure is in place to meet this requirement. Survey Procedures o Verify that the CAH has policies and procedures in place to ensure an MD/DO is available by telephone or radio, on a 24-hour a day basis to receive emergency calls and provide medical direction in emergency situations? o What evidence demonstrates that the procedures are followed and evaluated for effectiveness? o Interview staff to see how an MD/DO is contacted when emergency instructions are needed.

FED - C0210 - NUMBER OF BEDS AND LENGTH OF STAY

Title NUMBER OF BEDS AND LENGTH OF STAY

CFR 485.620

Type Condition

Regulation Definition	Interpretive Guideline
Number of Beds and Length of Stay	The CAH must ensure that specific number of beds and length of stay requirements are met.

FED - C0211 - NUMBER OF BEDS

Title NUMBER OF BEDS

CFR 485.620(a)

Type Standard

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Regulation Definition

Except as permitted for CAHs having distinct part units under §485.647, the CAH maintains no more than 25 inpatient beds after January 1, 2004, that can be used for either inpatient or swing-bed services.

Interpretive Guideline

All hospital-type beds will be counted to establish the number of beds regardless of admission status. The CAH may not have more than 25 beds that could be used for inpatient care. Any hospital-type bed located in or adjacent to any location where the bed could be used for inpatient care counts toward the 25 bed limit. Beds that do not count toward the 25 bed limit are:
o Examination or procedure tables;
o Stretchers, gurneys, litters;
(Note: stretchers occupied by patients and located in patients rooms will count toward the total bed count. Occupied stretchers being used in lieu of a hospital-type bed for the provision of care, no matter the location, will be counted toward the 25 bed count.)
o Operating room tables located in the operating room and used exclusively to conduct surgery on a patient;
o Beds in a surgical recovery room that are used exclusively for surgical patients during recovery from anesthesia;
o Newborn bassinets and isolettes used for well baby boarders; and
o Beds in Medicare a certified distinct part unit, and
o Beds in an obstetric delivery room that are used exclusively for observation of OB patients in active labor and delivery of newborn infants (do count beds in birthing rooms where the patient remains after giving birth); and
o Excess beds that are clearly in storage, are not in a patient room, are not available for immediate use, are not set up for use, and are not staffed for use.

Observation Patient Services
Observation services are defined as services furnished by a CAH to evaluate an outpatient's condition to determine the need for discharge or possible admission as an inpatient. An order is required.

Samples of appropriate use of observation status include:
o Following an ER visit to ensure the patient is stable;
o Following outpatient medical procedures;
o Following minor surgery; or
o Chest pain workup, asthma, or congestive heart failure treatments.

CAH regulations permit a CAH to have a distinct part psychiatric unit, a distinct part rehabilitation unit, and/or a distinct part SNF when those units meet Medicare requirements. There is no provision that recognizes a part of a CAH that is sometimes called a "distinct part observation unit". Patients is such units may receive the same type of care the CAH admits, therefore all beds in such an area will be counted as part of the CAH's total bed count.

The beneficiary may not be aware that observation stays fall under Part B and include expenses that the beneficiary will be billed for. The CAH must inform the beneficiary, prior to the stay, of any charges the beneficiary may

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reasonably be expected to pay out of pocket, including co-pays, deductibles, and meals.

Counting Hospice Patients in a CAH
A CAH can dedicate beds to a hospice under arrangement but the beds must count as part of the maximum bed count. The computation contributing to the 96 hour annual average length of stay does not apply to hospice patients. The hospice patient can be admitted to the CAH for any care involved in their hospice treatment plan or for respite care.

Medicare does not reimburse the CAH for the hospice CAH benefit. Medicare reimburses the hospice. The CAH must negotiate payment for services from the hospice through an agreement.

Survey Procedures
Count the hospital-type beds in each nursing unit. Count any hospital-type beds located in or adjoining any location where the bed could be used for inpatient care.

Do not count the following as a hospital-type bed:
o Examination or procedure tables;
o Stretchers;
o Operating room tables located in the operating room and used exclusively to conduct surgery on a patient;
o Beds in a surgical recovery room that are used exclusively for surgical patients during recovery from anesthesia;
o Beds in an obstetric delivery room that are used exclusively for observation of OB patients in active labor and delivery of newborn infants (do count beds in birthing rooms where the patient remains after giving birth); and
o Newborn bassinets and isolettes used for well baby boarders;
o Any beds in Medicare certified distinct part units; and
o Any furniture that is clearly in storage.

FED - C0212 - LENGTH OF STAY

Title LENGTH OF STAY

CFR 485.620(b)

Type Standard

Regulation Definition

The CAH provides acute inpatient care for a period that does not exceed, on an annual average basis, 96 hours per patient.

Interpretive Guideline

The Fiscal Intermediary (FI) will determine compliance with this CoP. The FI will calculate the CAH's length of stay based on patient census data. If a CAH exceeds the length of stay limit, the FI will send a report to the CMS-RO. The CAH will be required to develop and implement a plan of correction (POC) acceptable to the CMS Regional Office or provide adequate information to demonstrate compliance.

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FED - C0220 - PHYSICAL PLANT AND ENVIRONMENT

Title PHYSICAL PLANT AND ENVIRONMENT

CFR 485.623

Type Condition

Regulation Definition	Interpretive Guideline
Physical Plant and Environment	This CoP applies to all locations of the CAH, all campuses, all satellites, all provider-based activities, and all inpatient and outpatient locations. The CAH's departments or services responsible for the CAH's building and equipment maintenance (both facility equipment and patient care equipment) must be incorporated into the CAH's QA program and be in compliance with the QA requirements.

FED - C0221 - CONSTRUCTION

Title CONSTRUCTION

CFR 485.623(a)

Type Standard

Regulation Definition	Interpretive Guideline
The CAH is constructed, arranged, and maintained to ensure access to and safety of patients, and provides adequate space for the provision of direct services.	Physical facilities must be large enough, numerous enough, appropriately designed and equipped, and of appropriate complexity to provide the services offered in accordance with Federal and State laws, regulations and guidelines and accepted standards of practice for that location or service. Survey Procedures Verify through observation that the physical facilities are large enough and properly equipped for the scope of services provided and the number of patients served.

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FED - C0222 - MAINTENANCE

Title MAINTENANCE

CFR 485.623(b)(1)

Type Standard

Regulation Definition

The CAH has housekeeping and preventive maintenance programs to ensure that-

(1) all essential mechanical, electrical, and patient care equipment is maintained in safe operating condition;

Interpretive Guideline

The CAH must ensure that the condition of the physical plant and overall CAH environment is developed and maintained in a manner to ensure the safety and well being of patients. This includes ensuring that routine and preventive maintenance and testing activities are performed as necessary, in accordance with Federal and State laws, regulations, and guidelines and manufacturer's recommendations, by establishing maintenance schedules and conducting ongoing maintenance inspections to identify areas or equipment in need of repair. The routine and preventive maintenance and testing activities should be incorporated into the CAH's QA plan.

Facilities must be maintained to ensure an acceptable level of safety and quality.

Supplies must be maintained to ensure an acceptable level of safety and quality.

Equipment must be maintained to ensure an acceptable level of safety and quality.

Equipment includes both facility equipment (e.g., elevators, generators, air handlers, medical gas systems, air compressors and vacuum systems, etc.) and medical equipment (e.g., biomedical equipment, radiological equipment, patient beds, stretchers, IV infusion equipment, ventilators, laboratory equipment, etc.).

There must be a regular periodical maintenance and testing program for medical devices and equipment. A qualified individual such as a clinical or biomedical engineer, or other qualified maintenance person, must monitor, test, calibrate and maintain the equipment periodically in accordance with the manufacturer's recommendations and Federal and State laws and regulations. Equipment maintenance may be conducted using CAH staff, contracts, or through a combination of CAH staff and contracted services.

Survey Procedures
o Verify that the condition of the CAH is maintained in a manner to ensure the safety and well being of patients (e.g., condition or ceilings, walls, and floors, presence of patient hazards, etc.).
o Review the CAH's routine and preventive maintenance schedules to determine that ongoing maintenance inspections are performed and that necessary repairs are completed.

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o Interview the person in charge of medical equipment and determine if there is an adequate periodical maintenance and repair program.
o Verify that all medical devices and equipments are routinely checked by a clinical or biomedical engineer.
o Review maintenance logs for significant medical equipment (e.g., cardiac monitors, IV infusion pumps, ventilators, etc.).

FED - C0223 - MAINTENANCE

Title MAINTENANCE

CFR 485.623(b)(2)

Type Standard

Regulation Definition	Interpretive Guideline
[The CAH has housekeeping and preventive maintenance programs to ensure that--] (2) there is proper routine storage and prompt disposal of trash;	The term trash refers to common garbage as well as biohazardous waste. The storage and disposal of trash must be in accordance with Federal, State and local laws and regulations (i.e., EPA, OSHA, CDC, State environmental, health and safety regulations). The Radiology requirements address handling and storage of radioactive materials. Survey Procedures Verify that the CAH has developed and implemented policies for the proper storage and disposal of trash. Verify through observation that staff adhere to these policies and that the CAH has signage, as appropriate.

FED - C0224 - MAINTENANCE

Title MAINTENANCE

CFR 485.623(b)(3)

Type Standard

Regulation Definition	Interpretive Guideline
[The CAH has housekeeping and preventive maintenance programs to ensure that--] (3) drugs and biologicals are appropriately stored;	Survey Procedures What standards, guidelines, State and Federal law is the CAH following to ensure that drugs and biologicals are appropriately stored (e.g., properly locked) in all storage areas?

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FED - C0225 - MAINTENANCE

Title MAINTENANCE

CFR 485.623(b)(4)

Type Standard

Regulation Definition	Interpretive Guideline
[The CAH has housekeeping and preventive maintenance programs to ensure that- (4) the premises are clean and orderly;	"Clean and orderly" means an uncluttered physical environment where patients and staff can function safely (e.g., equipment and supplies stored in proper spaces, not in corridors, spills not left unattended or identified, no floor obstructions) and is neat and well-kept (e.g., no peeling paint, visible water leaks, plumbing problems).

FED - C0226 - MAINTENANCE

Title MAINTENANCE

CFR 485.623(b)(5)

Type Standard

Regulation Definition	Interpretive Guideline
[The CAH has housekeeping and preventive programs to ensure that- (5) there is proper ventilation, lighting, and temperature control in all pharmaceutical, patient care, and food preparation areas.	There must be proper ventilation in at least the following areas: o Areas using ethylene oxide, nitrous oxide, guteraldehydes, xylene, pentamidine, or other potentially hazardous substances; o Locations where oxygen is transferred from one container to another; o Isolation rooms and reverse isolation rooms (both must be in compliance with Federal and State laws, regulations, and guidelines such as OSHA, CDC, NIH, etc.); o Pharmaceutical preparation areas (hoods, cabinets, etc.); and o Laboratory locations. There must be adequate lighting in all the patient care, food and medication preparation areas. Temperature, humidity and airflow in the operating rooms must be maintained within acceptable standards to inhibit bacterial growth and prevent infection, and promote patient comfort. Excessive humidity in the operating room is conducive to bacterial growth and compromises the integrity of wrapped sterile instruments and supplies. Each

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operating room should have separate temperature control. Acceptable standards such as from the Association of Operating Room Nurses (AORN) or the American Institute of Architects (AIA) should be incorporated into CAH policy.

The CAH must ensure that an appropriate number of refrigerators and/or heating devices are provided and ensure that food and pharmaceuticals are stored properly and in accordance with nationally accepted guidelines (food) and manufacturer's recommendations (pharmaceuticals).

Survey Procedures
o Verify that all food and medication preparation areas are well lit.
o Verify that the CAH is in compliance with ventilation requirements for patients with contagious airborne diseases, such as tuberculosis, patients receiving treatments with hazardous chemical, surgical areas, and other areas where hazardous materials are stored.
o Verify that food products are stored under appropriate conditions (e.g., time, temperature, packaging, location) based on nationally accepted sources such as the United States Department of Agriculture, the Food and Drug Administration, or other nationally recognized standard.
o Verify that pharmaceuticals are stored at temperatures recommended by the product manufacturer.
o Verify that each operating room has temperature and humidity control mechanisms.
o Review temperature and humidity tracking logs to ensure that appropriate temperature and humidity levels are maintained.

FED - C0227 - EMERGENCY PROCEDURES

Title EMERGENCY PROCEDURES

CFR 485.623(c)(1)

Type Standard

Regulation Definition

[The CAH assures the safety of patients in non-medical emergencies by-]

(1) training staff in handling emergencies, including prompt reporting of fires, extinguishing of fires, protection and, where necessary, evacuation of patients, personnel, and guests, and cooperation with fire fighting and disaster authorities;

Interpretive Guideline

Survey Procedures
o How does the CAH ensure that all personnel on its staff, including new additions to the staff, are trained to manage non-medical emergencies?
o Ask facility staff what they are supposed to do in case of an emergency such as a tornado or a blizzard.
o Review staff training documents and inservice records to validate training.
o Review the CAH's written fire control plans to verify they contain the required provisions of the Life Safety Code or State law.
o Verify that CAH staff reported all fires to State officials as required.

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o Interview staff throughout the facility to verify their knowledge of their responsibilities during a fire (this is usually done during the LSC survey, but health surveyors may also verify staff knowledge).

FED - C0228 - EMERGENCY PROCEDURES

Title EMERGENCY PROCEDURES

CFR 485.623(c)(2)

Type Standard

Regulation Definition	Interpretive Guideline
[The CAH assures the safety of patients in non-medical emergencies by-]	The CAH must comply with the applicable provisions of the Life Safety Code, National Fire Protection Amendments (NFPA) 101, 2000 Edition and applicable references such as NFPA-99: Health Care Facilities, for emergency lighting and emergency power.
(2) providing for emergency power and lighting in the emergency room and for battery lamps and flashlight in other areas;	Survey Procedures Use the Life Safety Code Survey Report Form (CMS-2786) to evaluate compliance with this item.

FED - C0229 - EMERGENCY PROCEDURES

Title EMERGENCY PROCEDURES

CFR 485.623(c)(3)

Type Standard

Regulation Definition	Interpretive Guideline
[The CAH assures the safety of patients in non-medical emergencies by--]	The CAH must have a system to provide emergency gas and water as needed to provide care to inpatients and other persons who may come to the CAH in need of care. This includes making arrangements with local utility companies and others for the provision of emergency sources of water and gas. The CAH should consider nationally accepted references or calculations made by qualified staff when determining the need for water and gas. For example, one source for information on water is the Federal Emergency Management Agency (FEMA). Emergency gases include fuels such as propane, natural gas, fuel oil, liquefied natural gas, as well as any gases the CAH uses in the care of patients such as oxygen, nitrogen, nitrous oxide, etc. The CAH should have a plan to protect these limited emergency supplies, and have a plan for prioritizing their use
(3) providing for an emergency fuel and water supply; and.	

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until adequate supplies are available. The plan should also address the event of a disruption in supply (e.g., disruption to the entire surrounding community).

Survey Procedures
o Review the system used by CAH staff to determine the CAH's emergency needs for gas and water. Verify that the system accounts for not only inpatients, but also staff and other persons who come to the CAH in need of care during emergencies.
o Determine the source of emergency gas and water, both the quantity of these supplies readily available at the CAH, and those that may be needed within a short time through additional deliveries.
o Verify that arrangements have been made with utility companies and others for the provision of emergency sources of critical utilities such as water and gas.

FED - C0230 - EMERGENCY PROCEDURES

Title EMERGENCY PROCEDURES

CFR 485.623(c)(4)

Type Standard

Regulation Definition

[The CAH assures the safety of patients in non-medical emergencies by--]

(4) taking other appropriate measures that are consistent with the particular conditions of the area in which the CAH is located.

Interpretive Guideline

Assuring the safety and well being of patients would include developing and implementing appropriate emergency preparedness plans and capabilities. The CAH must develop and implement a comprehensive plan to ensure that the safety and well being of patients are assured during emergency situations. The CAH must coordinate with Federal, State, and local emergency preparedness and health authorities to identify likely risks for their area (e.g., natural disasters, bioterrorism threats, disruption of utilities such as water, sewer, electrical communications, fuel, nuclear accidents, industrial accidents, and other likely mass casualties, etc.) and to develop appropriate responses that will ensure the safety and well being of patients. The following issues should be considered when developing the comprehensive emergency plans(s):
o Differences needed for each location where the certified CAH operates;
o The special needs of patient populations treated at the CAH (e.g., patients with psychiatric diagnosis, patients on special diets, newborns, etc.);
o Security of patients and walk-in patients;
o Security of supplies from misappropriation;
o Pharmaceuticals, food, other supplies and equipment that may be needed during emergency/disaster situations;
o Communication to external entities if telephones and computers are not operating or become overloaded (e.g., ham radio operators, community officials, other healthcare facilities if transfer of patients is necessary, etc.);
o Communication among staff within the CAH itself;

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o Qualifications and training needed by personnel, including healthcare staff, security staff, and maintenance staff, to implement and carry out emergency procedures;
o Identification, availability and notification of personnel that are needed to implement and carry out the CAH's emergency plans;
o Identification of community resources, including lines of communication and names and contact information for community emergency preparedness coordinators and responders;
o Provisions for gas, water, electricity supply if access is shut off to the community;
o Transfer or discharge of patients to home or other healthcare settings; and
o Methods to evaluate repairs needed and to secure various likely materials and supplies to effectuate repairs.

Survey Procedures
Verify that the CAH has developed and implemented a comprehensive plan to ensure the safety and well being of patients during local emergency situations.

FED - C0231 - LIFE SAFETY FROM FIRE

Title LIFE SAFETY FROM FIRE

CFR 485.623(d)(1)

Type Standard

Regulation Definition

Except as otherwise provided in this section-
(i) the CAH must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html.
Copies may be obtained from the National Fire Protection

Interpretive Guideline

Medicare-participating CAHs, regardless of size or number of beds, must comply with the Hospital/healthcare Life Safety Code requirements for all inpatient care locations. Departments and locations of the CAH such as emergency departments, outpatient care locations, etc. must comply with Hospital/healthcare Life Safety Code Requirements. Additionally, the CAH must be in compliance with all applicable codes referenced in the Life Safety Code, such as NFPA-99 Health Care Facilities.

This revision adopts the 2000 edition of the LSC and deletes provisions for the use of roller latches in the facility.

Survey Procedures
o There is a separate survey form (CMS-2786) used by the Fire Authority surveyor to evaluate compliance with the Life Safety Code and a separate 1985 Life Safety Code Addendum to be used when surveying for compliance with the 1985 Life Safety Code. (Life Safety Code Guidelines and a copy of the 1985 Life Safety Code Addendum are contained in SOM Appendix I.)
o Survey the entire building occupied by the CAH unless there is a 2-hour firewall separating the space designated as the CAH from the remainder of the building. A 2-hour floor slab does not count; it must be a vertical firewall to

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Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the Federal Register to announce the changes.

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the Life Safety Code does not apply to a CAH.

constitute a separate building or part of a building

FED - C0234 - LIFE SAFETY FROM FIRE

Title LIFE SAFETY FROM FIRE

CFR 485.623(d)(4)

Type Standard

Regulation Definition

The CAH maintains written evidence of regular inspection and approval by State or local fire control agencies.

Interpretive Guideline

Survey Procedures
Examine copies of inspection and approval reports from State and local fire control agencies.

FED - C0235 - LIFE SAFETY FROM FIRE

Title LIFE SAFETY FROM FIRE

CFR 485.623(d)(5)

Type Standard

Regulation Definition

Beginning March 13, 2006, a critical access hospital must be in compliance with Chapter 9.2.9, Emergency Lighting. Beginning March 13, 2006, Chapter 19.3.6.3.2, exception 2 does not apply to critical access hospitals.

Interpretive Guideline

CAHs should develop plans for compliance with this requirement so that in all applicable locations roller latches have been replaced by positive latches prior to March 13, 2006.

These sections allow facilities until March 13, 2006, to replace roller latches and to replace 1 hour batteries with 1-1/2 hour batteries in emergency lighting systems that use batteries as power sources.

After March 13, 2006 a CAH with doors in service with roller latches or with emergency lighting systems with less than 1-1/2 hour batteries will not be in compliance and will be cited at 485.623(d)(1).

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FED - C0236 - LIFE SAFETY FROM FIRE

Title LIFE SAFETY FROM FIRE

CFR 485.623(d)(6)

Type Standard

Regulation Definition	Interpretive Guideline
Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to critical access hospitals.	

FED - C0237 - LIFE SAFETY FROM FIRE

Title LIFE SAFETY FROM FIRE

CFR 485.623(d)(7)

Type Standard

Regulation Definition	Interpretive Guideline
Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a critical access hospital may install alcohol based hand rub dispensers in its facility if- (i) Use of alcohol-based hand rub dispensers does not conflict with any State of local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities; (ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls; (iii) The dispensers are installed in a manner that adequately protects against inappropriate access; and (iv) The dispensers are installed in accordance with chapter 18.3.2.7 of chapter 19.3.2.7 of the 2000 Life Safety Code, as amended by NFPA Temporary Interim Amendment 00-01(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director	

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of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00-01(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Association, 1 Batterymarch Park, Quincy, MA 02269; and (v) The dispensers are maintained in accordance with dispenser manufacturer guidelines.

FED - C0240 - ORGANIZATIONAL STRUCTURE

Title ORGANIZATIONAL STRUCTURE

CFR 485.627

Type Condition

Regulation Definition	Interpretive Guideline
Organizational Structure	The CAH must ensure that the organizational structure requirements are met.

FED - C0241 - GOVERNING BODY OR RESPONSIBLE INDIVIDUAL

Title GOVERNING BODY OR RESPONSIBLE INDIVIDUAL

CFR 485.627(a)

Type Standard

Regulation Definition	Interpretive Guideline
The CAH has a governing body or an individual that assumes full legal responsibility for determining, implementing, and monitoring policies governing the CAH's total operation and for ensuring that those policies are administered so as to provide quality health care in a safe environment.	The CAH must have only one governing body (or responsible individual) and this governing body (or responsible individual) is responsible for the conduct of the CAH as an institution. In the absence of an organized governing body, there must be written documentation that identifies the individual or individuals that are responsible for the conduct of the CAH operations. The governing body (or responsible individual) must determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff.

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It is the responsibility of the governing body (or responsible individual) to appoint, with the advice of the medical staff, the individual practitioners to the medical staff. After considering medical staff recommendations, and in accordance with established CAH medical staff criteria and State and Federal laws and regulations, the governing body (or responsible individual) decides whether or not to appoint new medical staff members or to continue current members of the medical staff.

The governing body (or responsible individual) must ensure that the medical staff has bylaws that comply with State and Federal law and the requirements of the CAH CoP.

The governing body (or responsible individual) decides whether or not to approve medical staff bylaws submitted by the medical staff. The medical staff bylaws and any revisions must be approved by the governing body (or responsible individual) before they are considered effective.

The governing body (or responsible individual) must ensure that the medical staff is accountable to the governing body (or responsible individual) for the quality of care provided to patients. The governing body (or responsible individual) is responsible for the conduct of the CAH and this conduct would include the quality of care provided to patients.

All CAH patients must be under the care of a member of the medical staff or under the care of a practitioner who is under the supervision of a member of the medical staff. All patient care is provided by or in accordance with the orders of a practitioner granted privileges to provide or order that care and is in accordance with State law.

Criteria for selection of both new medical staff members and selection of current medical staff members for continued membership must be based on:
o Individual character;
o Individual competence;
o Individual training;
o Individual experience; and
o Individual judgment

Survey Procedures
o Verify that the CAH has an organized governing body or has written documentation that identifies the individual that is responsible for the conduct of the CAH operations.
o Review documentation and verify that the governing body (or responsible individual) has determined and stated the

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categories of practitioners that are eligible candidates for appointment to the medical staff.
o Have the facility's operating policies been updated to fully reflect its responsibilities as a CAH (e.g., PA responsibilities, provision of required CAH direct services)?
o What evidence (e.g., minutes of board meetings) demonstrates that the governing body or the individual who assumes responsibility for CAH operation is involved in the day-to-day operation of the CAH and is fully responsible for its operations?
o Evaluate records of medical staff appointments to substantiate the governing body's (or responsible individual's) involvement in appointments of medical staff members.
o Confirm that the governing body (or responsible individual) appoints all members to the medical staff in accordance with established policies based on the individual practitioner's scope of clinical expertise and in accordance with Federal and State law.
o Verify that the medical staff operates under current bylaws that are in accordance with Federal and State laws and regulations.
o Verify that the medical staff operates under current bylaws, rules and policies that have been approved by the governing body (or responsible individual).
o Verify that any revisions or modifications in the medical staff bylaws, rules, and policies, have been approved by the medical staff and the governing body (or responsible individual). For example, look at the bylaws and check for date of last review and initials by the person(s) responsible.
o Verify that the governing body (or responsible individual) is periodically apprised of the medical staff evaluation of patient care services provided in the CAH, at every patient care location of the CAH.
o Verify that any individual providing patient care services is a member of the medical staff or is accountable to a member of the medial staff qualified to evaluate the quality of services provided, and in turn, is responsible to the governing body (or responsible individual) for the quality of services provided.
o Verify that there are written criteria for staff appointments to the medical staff.
o Verify that selection of medical staff for membership, both new and renewal, is based upon an individual practitioner's compliance with the medical staff's membership criteria.
o Verify that at a minimum, criteria for selection to the medical staff are individual character, competence, training, experience, and judgment.

FED - C0242 - DISCLOSURE

Title DISCLOSURE

CFR 485.627(b)(1)

Type Standard

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Regulation Definition	Interpretive Guideline
The CAH discloses the names and addresses of- (1) its owners, or those with a controlling interest in the CAH or in any subcontractor in which the CAH directly or indirectly has a 5 percent or more ownership interest, in accordance with Subpart C of part 420 of this chapter.	Survey Procedures o Review CAH policy for reporting changes of ownership. o How does the CAH implement its policy or procedure for reporting changes in ownership to the State agency?

FED - C0243 - DISCLOSURE

Title DISCLOSURE

CFR 485.627(b)(2)

Type Standard

Regulation Definition	Interpretive Guideline
[The CAH discloses the name and addresses of--] (2) the person principally responsible for the operation of the CAH; and	Survey Procedures How does the CAH implement its policy or procedure for reporting changes in operating officials to the State agency?

FED - C0244 - DISCLOSURE

Title DISCLOSURE

CFR 485.627(b)(3)

Type Standard

Regulation Definition	Interpretive Guideline
[The CAH discloses the name and addresses of--] (3) the person responsible for medical direction	Survey Procedures How does the CAH implement its policy or procedure for reporting changes in medical director to the State agency?

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FED - C0250 - STAFFING AND STAFF RESPONSIBLITIES

Title STAFFING AND STAFF RESPONSIBLITIES

CFR 485.631

Type Condition

Regulation Definition	Interpretive Guideline
Staffing and Staff Responsibilties	The CAH must ensure that the staffing and staffing responsibilities requirements are met.

FED - C0251 - STAFFING

Title STAFFING

CFR 485.631(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The CAH has a professional health care staff that includes one or more doctors of medicine or osteopathy and may include one or more physician assistants, nurse practitioners, or clinical specialists.	A CAH may operate with all MD/DOs on staff as well as with any combination of mid-level practitioners and physicians. Survey Procedures o Review listings or organizational charts showing the names of all staff MD/DOs, nurse practitioners, clinical nurse specialists and physician assistants on the CAH staff. o Review work schedules showing normal CAH hours of operation and coverage by members of the CAH staff.

FED - C0252 - STAFFING

Title STAFFING

CFR 485.631(a)(2)

Type Standard

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Regulation Definition	Interpretive Guideline
Any ancillary personnel are supervised by the professional staff.	Survey Procedures Use organizational charts and staff interviews to determine how the CAH ensures that the professional staff supervises all ancillary personnel.

FED - C0253 - STAFFING

Title STAFFING

CFR 485.631(a)(3)

Type Standard

Regulation Definition	Interpretive Guideline
The staff is sufficient to provide the services essential to the operation of the CAH.	Survey Procedures o How does the CAH ensure that staff coverage is sufficient to provide essential services at the facility (e.g., emergency services, direct services, and nursing services)? o Review staffing schedules and daily census records.

FED - C0254 - STAFFING

Title STAFFING

CFR 485.631(a)(4)

Type Standard

Regulation Definition	Interpretive Guideline
A doctor of medicine or osteopathy, nurse practitioner, clinical nurse specialist, or physician assistant is available to furnish patient care services at all times the CAH operates.	Section 485.635(b)(1) requires CAHs to provide "those diagnostic and therapeutic services and supplies that are commonly furnished in "a physicians office" such as low intensity outpatient services. In order to demonstrate compliance, a CAH must demonstrate that a practitioner is physically present and prepared to treat patients at the CAH when patients present at the CAH outpatient clinic during announced hours of outpatient clinic operation. This requirement does not mean the CAH must have a practitioner physically present in the facility 24 hours per day, nor does it require their presence 24 hours per day when the CAH has inpatients, including swing-bed patients. Survey Procedures o If the CAH does not have regularly announced hours of operation, ask the individual who is principally responsible

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for the operation of the CAH, when is the CAH is open to the public to provide outpatient services.
o What kinds of arrangements have been made by the CAH to ensure that a practitioner is available on site at all times the CAH operates to furnish patient care services?

FED - C0255 - STAFFING

Title STAFFING

CFR 485.631(a)(5)

Type Standard

Regulation Definition	Interpretive Guideline
A registered nurse, clinical nurse specialist, or licensed practical nurse is on duty whenever the CAH has one or more inpatients.	Survey Procedures Review nursing staff schedules to ensure that a registered nurse, clinical nurse specialist or licensed practical nurse is on duty whenever the CAH has one or more inpatients.

FED - C0256 - RESPONSIBILITIES OF MD OR DO

Title RESPONSIBILITIES OF MD OR DO

CFR 485.631(b)

Type Standard

Regulation Definition	Interpretive Guideline
Responsibilities of MD or DO	The CAH must ensure that the responsibilities of the Doctor of Medicine or Osteopathy requirements are met.

FED - C0257 - RESPONSIBILITIES OF MD OR DO

Title RESPONSIBILITIES OF MD OR DO

CFR 485.631(b)(1)(i)

Type Standard

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Regulation Definition	Interpretive Guideline
The doctor of medicine or osteopathy- (i) provides medical direction for the CAH's health care activities and consultation for, and medical supervision of, the health care staff;	A CAH must have an MD/DO on its staff. That individual must perform all of the medical oversight functions. Survey Procedures What evidence demonstrates that an MD/DO provides medical direction for the CAH's health care activities and is available for consultation and supervision of the CAH health care staff?

FED - C0258 - RESPONSIBILITIES OF MD OR DO

Title RESPONSIBILITIES OF MD OR DO

CFR 485.631(b)(1)(ii)

Type Standard

Regulation Definition	Interpretive Guideline
[The doctor of medicine or osteopathy-] (ii) in conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the CAH's written policies governing the services it furnishes;	Survey Procedures o What evidence demonstrates that an MD/DO has participated in the development of policies governing CAH services? o How does the CAH ensure that an MD/DO periodically reviews these policies?

FED - C0259 - RESPONSIBILITIES OF MD OR DO

Title RESPONSIBILITIES OF MD OR DO

CFR 485.631(b)(1)(iii)

Type Standard

Regulation Definition	Interpretive Guideline
[The doctor of medicine or osteopathy-] (iii) in conjunction with the physician assistant and/or nurse practitioner members, periodically reviews the CAH's patient records, provides medical orders, and provides medical care	Survey Procedures o How does the CAH ensure that an MD/DO periodically reviews CAH patient records in conjunction with staff mid-level practitioners and provides medical care to CAH patients? o What evidence demonstrates that there is a periodic review of patient records by the CAH MD/DO(s)?

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services to the patients of the CAH; [and]

FED - C0260 - RESPONSIBILITIES OF MD OR DO

Title RESPONSIBILITIES OF MD OR DO

CFR 485.631(b)(1)(iv)

Type Standard

Regulation Definition	Interpretive Guideline
[The doctor of medicine or osteopathy-] (iv) Periodically reviews and signs the records of all inpatients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants.	Survey Procedures Select a sample of inpatient and outpatient records, including open and closed records as well as inpatient and outpatient records. Verify that a MD/DO has reviewed and signed all records for patients cared for by mid-level practitioners. CRNAs are not considered to be nurse practitioners by Medicare, they are anesthesia practitioners. This requirement does not apply to CRNA.

FED - C0261 - RESPONSIBILITIES OF MD OR DO

Title RESPONSIBILITIES OF MD OR DO

CFR 485.631(b)(1)(v)

Type Standard

Regulation Definition	Interpretive Guideline
[The doctor of medicine or osteopathy-] (v) Periodically, but not less than every 2 weeks, reviews and signs a sample of outpatient records of patients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants according to the policies of the CAH and according to current standards of practice where State law requires record review.	An MD/DO must visit a CAH often enough to provide medical oversight for all patient services provided at the CAH in accordance with the scope of services provided. Survey Procedures o What documentation shows that an MD/DO visits the facility at least once every 2 weeks? o How does the CAH ensure that an MD/DO is available by telephone or radio contact for consultation, assistance and/or patient referral?

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FED - C0262 - RESPONSIBILITIES OF MD OR DO

Title RESPONSIBILITIES OF MD OR DO

CFR 485.631(b)(1)(vi)

Type Standard

Regulation Definition	Interpretive Guideline
[The doctor of medicine or osteopathy-] (vi) Is not required to review and sign outpatient records of patients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants where State law does not require record reviews or co-signatures, or both, by a collaborating physician.	

FED - C0263 - RESPONSIBILITIES OF MD OR DO

Title RESPONSIBILITIES OF MD OR DO

CFR 485.631(b)(2)

Type Standard

Regulation Definition	Interpretive Guideline
A doctor of medicine or osteopathy is present for sufficient periods of time, at least once in every 2 week period (except in extraordinary circumstances) to provide the medical direction, medical care services, consultation, and supervision described in this paragraph, and is available through direct radio or telephone communication for consultation, assistance with medical emergencies, or patient referral. The extraordinary circumstances are documented in the records of the CAH. A site visit is not required if no patients have been treated since the last site visit.	Survey Procedures o Interview any mid-level professional staff to ascertain their level of involvement in CAH policy development, execution, and periodic review. o Does the CAH ensure that policies are updated to remain consistent with State standards of practice requirements for mid-level practitioners?

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FED - C0264 - PA, NP & NURSE SPECIALIST RESPONSIBILITIES

Title PA, NP & NURSE SPECIALIST RESPONSIBILITIES
CFR 485.631(c)

Type Standard

Regulation Definition	Interpretive Guideline
Physician Assistant, Nurse Practitioner, or Clinical Nurse Specialist Responsibilities	

FED - C0265 - PA, NP & NURSE SPECIALIST RESPONSIBILITIES

Title PA, NP & NURSE SPECIALIST RESPONSIBILITIES
CFR 485.631(c)(1)(i)

Type Standard

Regulation Definition	Interpretive Guideline
(1)The physician assistant, nurse practitioner, or clinical nurse specialist members of the CAH's staff- (i) participate in the development, execution and periodic review of the written policies governing the services the CAH furnishes; [and]	Survey Procedures o Review policies and procedures. o Interview mid-level practitioners to gauge their knowledge and application of CAH policies.

FED - C0266 - PA, NP & NURSE SPECIALIST RESPONSIBILITIES

Title PA, NP & NURSE SPECIALIST RESPONSIBILITIES
CFR 485.631(c)(1)(ii)

Type Standard

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Regulation Definition	Interpretive Guideline
[The physician assistant, nurse practitioner, or clinical nurse specialist members of the CAH's staff-] (ii) participate with a doctor of medicine or osteopathy in a periodic review of the patients' health records.	

FED - C0267 - PA, NP & NURSE SPECIALIST RESPONSIBILITIES

Title PA, NP & NURSE SPECIALIST RESPONSIBILITIES
CFR 485.631(c)(2)(i)

Type Standard

Regulation Definition	Interpretive Guideline
(2) The physician assistant, nurse practitioner, or clinical nurse specialist performs the following functions to the extent they are not being performed by a doctor of medicine or osteopathy: (i) provides services in accordance with the CAH's policies.	Survey Procedures Verify that there are policies and procedures for transferring patients to other facilities.

FED - C0268 - PA, NP & NURSE SPECIALIST RESPONSIBILITIES

Title PA, NP & NURSE SPECIALIST RESPONSIBILITIES
CFR 485.631(c)(2)(ii)

Type Standard

Regulation Definition	Interpretive Guideline
The physician assistant, nurse practitioner, or clinical nurse specialist performs the following functions to the extent they are not being performed by a doctor of medicine or osteopathy:	The CAH regulations do permit licensed mid-level practitioners, as allowed by the State, to admit patients to a CAH. However, CMS regulations do require that Medicare and Medicaid patients be under the care of an MD/DO if admitted by a mid-level practitioner and the patient has any medical or psychiatric problem that is present on admission or develops during hospitalization that is outside the scope of practice of the admitting practitioner. Evidence of being under the care of an MD/DO must be in the patient's medical record. If a CAH allows a mid-level

practitioner to admit and care for patients, as allowed by State law, the governing body (or responsible individual) and medical staff would have to establish policies and bylaws to ensure patient safety. As applicable, the patient's medical record must demonstrate MD/DO responsibility/care.

Survey Procedures
o Verify that admitting privileges are limited to those categories of practitioners as allowed by State law.
o Verify that patients are admitted only by those practitioners who are currently licensed and have been granted admitting privileges by the governing body (or responsible individual) in accordance with State laws and medical staff bylaws.
o Verify that an MD/DO is responsible for and is monitoring the care of each Medicare or Medicaid patient for all medical problems during the hospitalization.
o If mid-level practitioners admit patients, verify that every Medicare/Medicaid patient is being monitored by an MD/DO who is responsible for any medical problem outside the scope of practice of the admitting practitioners.

FED - C0269 - PA, NP & NURSE SPECIALIST RESPONSIBILITIES

Title PA, NP & NURSE SPECIALIST RESPONSIBILITIES
CFR 485.631(c)(3)

Type Standard

Regulation Definition

Whenever a patient is admitted to the CAH by a nurse practitioner, physician assistant, or clinical nurse specialist, a doctor of medicine or osteopathy on the staff of the CAH is notified of the admission.

Interpretive Guideline

The CAH regulations do permit licensed mid-level practitioners, as allowed by the State, to admit patients to a CAH. However, CMS regulations do require that Medicare and Medicaid patients be under the care of an MD/DO if admitted by a mid-level practitioner and the patient has any medical or psychiatric problem that is present on admission or develops during hospitalization that is outside the scope of practice of the admitting practitioner. Evidence of being under the care of an MD/DO must be in the patient's medical record. If a CAH allows a mid-level practitioner to admit and care for patients, as allowed by State law, the governing body (or responsible individual) and medical staff would have to establish policies and bylaws to ensure patient safety. As applicable, the patient's medical record must demonstrate MD/DO responsibility/care.

Survey Procedures
o Verify that admitting privileges are limited to those categories of practitioners as allowed by State law.
o Verify that patients are admitted only by those practitioners who are currently licensed and have been granted admitting privileges by the governing body (or responsible individual) in accordance with State laws and medical staff bylaws.
o Verify that an MD/DO is responsible for and is monitoring the care of each Medicare or Medicaid patient for all

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medical problems during the hospitalization.
o If mid-level practitioners admit patients, verify that every Medicare/Medicaid patient is being monitored by an MD/DO who is responsible for any medical problem outside the scope of practice of the admitting practitioners.

FED - C0270 - PROVISION OF SERVICES

Title PROVISION OF SERVICES

CFR 485.635

Type Condition

Regulation Definition	Interpretive Guideline
Provision of Services	The CAH must ensure that the provision of services requirements are met.

FED - C0271 - PATIENT CARE POLICIES

Title PATIENT CARE POLICIES

CFR 485.635(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The CAH's health care services are furnished in accordance with appropriate written policies that are consistent with applicable State law.	Survey Procedures o Review CAH health care services policies and sampled records. o Observe staff delivering health care services to patients. o What evidence indicates that patients are receiving care in accordance with written policies for health care services consistent with applicable State law?

FED - C0272 - PATIENT CARE POLICIES

Title PATIENT CARE POLICIES

CFR 485.635(a)(2)

Type Standard

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Regulation Definition	Interpretive Guideline
(2) The policies are developed with the advice of a group of professional personnel that includes one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff under the provisions of §485.631(a)(1); at least one member is not a member of the CAH staff.	A CAH with a full time physician is not required to have a mid-level practitioner on staff, and therefore, would not have to obtain the services of a mid-level practitioner on a contractual or voluntary basis to participate in writing the facility's health care services policies. Survey Procedures o Review any meeting minutes to determine group composition and to ascertain the extent of the group's interactions with the CAH. o Interview the Director of Nursing to determine the extent of his/her interactions with this group concerning policy development.

FED - C0273 - PATIENT CARE POLICIES

Title PATIENT CARE POLICIES

CFR 485.635(a)(3)(i)

Type Standard

Regulation Definition	Interpretive Guideline
The policies include the following: (i) a description of the services the CAH furnishes directly and those furnished through agreement or arrangement.	Policies should clearly explain what types of health care services are available at the CAH and which services are furnished through agreements or arrangements. For example, statements like "taking complete medical histories, providing complete physical examinations, laboratory tests including" (with a list of tests provided) would satisfy this requirement. Arrangement and agreements include services provided through formal contracts, joint ventures, informal agreements, or lease arrangements. Additional services furnished through referral should be clearly described in statements such as: "arrangements have been made with Hospital X for CAH patients to receive the following services" (with a specific list of specialized diagnostic and laboratory testing, or specialized therapy).

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FED - C0274 - PATIENT CARE POLICIES

Title PATIENT CARE POLICIES

CFR 485.635(a)(3)(ii)

Type Standard

Regulation Definition	Interpretive Guideline
[The policies include the following:]	Policies should show how the CAH would meet all of its emergency services requirements.
(ii) policies and procedures for emergency medical services	

FED - C0275 - PATIENT CARE POLICIES

Title PATIENT CARE POLICIES

CFR 485.635(a)(3)(iii)

Type Standard

Regulation Definition	Interpretive Guideline
[The policies include the following:]	Guidelines for the medical management of health problems should include a description of the scope of medical acts that may be performed by the mid-level practitioners. Guidelines represent an agreement between the MD/DO providing the CAH's medical direction and the CAH's mid-level practitioners relative to the privileges and limits of those acts of medical diagnosis and treatment that may be undertaken with direct MD/DO supervision.
(iii) guidelines for the medical management of health problems that include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the CAH.	Guidelines should describe the regimens to follow and also stipulate the condition in the illness or health care management when consultation or referral is required. Regardless of the format used by the CAH for its medical management guidelines, they should include the following essential elements. o The policies should be comprehensive enough to cover most health problems that patients usually refer to a MD/DO. o The policies should describe the medical procedures available to the PA, NP and/or CNS. o The policies should describe the medical conditions, signs, or developments that require consultation or referral. o The policies should be compatible with State laws.

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Survey Procedures
o What evidence demonstrates that the CAH's guidelines for medical management of health problems accurately reflect the actual clinical capabilities of the facility?
o What evidence demonstrates that the guidelines are followed?

FED - C0276 - PATIENT CARE POLICIES

Title PATIENT CARE POLICIES

CFR 485.635(a)(3)(iv)

Type Standard

Regulation Definition

[The policies include the following:]

(iv) rules for the storage, handling, dispensation, and administration of drugs and biologicals. These rules must provide that there is a drug storage area that is administered in accordance with accepted professional principles, that current and accurate records are kept of the receipt and disposition of all scheduled drugs, and that outdated, mislabeled, or otherwise unusable drugs are not available for patient use.

Interpretive Guideline

Pharmaceutical services must be administered in accordance with accepted professional principles. Accepted professional principles include compliance with applicable Federal and State laws, regulations, and guidelines governing pharmaceutical services, as well as, standards or recommendations promoted by nationally recognized professional organizations such as the American Society of Health-System Pharmacists (ASHP).

A fundamental purpose of pharmaceutical services is to ensure the safe and appropriate use of medications and medication-related devices. The pharmacy director, with input from appropriate CAH staff and committees, develops, implements and periodically reviews and revises policies and procedures governing provision of pharmaceutical services.

Methods a CAH uses to maintain professional principles include:
o Policies and procedures have been developed and are being followed;
o Drugs and biologicals are stored in accordance with manufacturer's directions and State and Federal requirements;
o Employees provide pharmaceutical services within their scope of license and education;
o Pharmacy records have sufficient detail to follow the flow of pharmaceuticals from their entry into the CAH through dispensation and administration;
o The pharmacy maintains controls over drugs and medications in all CAH locations, including floor stock;
o Maintaining pharmacy and accounting records pertaining to the requisitioning and dispensing of drugs and pharmaceutical supplies;
o Ensuring that drugs are being dispensed only by a licensed pharmacist; and
o Only pharmacists or pharmacy-supervised personnel compound, label and dispense drugs or biologicals.

Pharmaceutical services at a CAH can be provided either as direct services or through an agreement. The direction

of pharmaceutical services may not require continuous on-premise supervision at the CAH's pharmacy but may be accomplished through regularly scheduled visits, and/or telemedicine in accordance with Federal and State law and regulation and accepted professional principles.

A single pharmacist must be responsible for the overall administration of the pharmacy service whether employed by the CAH or obtained through agreement. The pharmacist must be responsible for developing, supervising, and coordinating all the activities of the CAH-wide pharmacy service and must be thoroughly knowledgeable about CAH pharmacy practice and management.

The job description or the written agreement for the responsibilities of the pharmacist should be clearly defined and include development, supervision and coordination of all the activities of pharmacy services.

Pharmacists and pharmacy technicians must perform their duties within the scope of their license and education. There must be sufficient personnel to respond to the pharmaceutical needs of the patient population being served. The pharmaceutical services staff must be sufficient in types, numbers, and training to provide quality services, including 24 hour, 7-day emergency coverage, or there may be an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff.

There must be sufficient numbers and types of personnel to provide accurate and timely medication delivery, ensure accurate and safe medication administration and to provide appropriate clinical services as well as the participation in continuous quality improvement programs that meet the needs of the patient population being served.

The CAH must have a system that ensures that medication orders get to the pharmacy and drugs get back to patients promptly.

Record System
Components of a record system to maintain current and accurate records of the receipt and disposition of scheduled drugs would include:
o Accountability procedures to ensure control of the distribution, use, and disposition of all scheduled drugs.
o Records of the receipt and disposition of all scheduled drugs must be current and must be accurate.
o Records trace the movement of scheduled drugs throughout the service.

The pharmacist is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled.

The record system, delineated in policies and procedures, tracks movement of all scheduled drugs from the point of entry into the CAH to the point of departure either through administration to the patient, destruction of the drug, or return to the manufacturer. This system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.

The CAH system should be capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual losses or diversion to the time of detection and determination of the extent of loss or diversion.

Facility policies and procedures should minimize scheduled drug diversion.

Receipt and Distribution of Drugs
Drugs and biologicals must be controlled and distributed in accordance with applicable Federal and State laws and regulations, and in accordance with applicable standards of practice. Applicable standards of practice include compliance with all Federal and State laws, regulations, and guidelines, as well as, standards and recommendations promoted by nationally recognized professional organizations, that apply to pharmaceutical safety and the control and distribution of drugs and biologicals.

The procedures established to prevent unauthorized usage and distribution must provide for an accounting of the receipt and disposition of drugs subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970.

The pharmacist, in consultation with appropriate CAH staff and committees, is to develop and implement guidelines, protocols, policies and procedures for the provision of pharmaceutical services that ensure patient safety through the appropriate control and distribution of medications, medication-related devices, and biologicals.

All prescribers' medication orders (except in emergency situations) should be reviewed for appropriateness by a pharmacist before the first dose is dispensed, or as soon as possible in the case of very small and remote CAHs.

Appropriate monitoring of medication therapy should be conducted. Medication-therapy monitoring includes an assessment of:
o Therapeutic appropriateness of a patient's medication regimen;
o Therapeutic duplication in the patient's medication regimen;
o Appropriateness of the route and method of administration;
o Medication-medication, medication-food, medication-laboratory test and medication-disease interactions;
o Clinical and laboratory data to evaluate the efficacy of medication therapy to anticipate or evaluate toxicity and

adverse effects; and
o Physical signs and clinical symptoms relevant to the patient's medication therapy.

Sterile products should be prepared and labeled in a suitable environment by appropriately trained and qualified personnel.

The pharmacy should participate in CAH decisions about emergency medication kits. The supply and provision of emergency medications stored in the kits must be consistent with standards of practice and appropriate for a specified age group or disease treatment as well as consistent with applicable Federal and State laws.

The pharmacy should be involved in the evaluation, use and monitoring of drug delivery systems, administration devices and automated drug-dispensing machines. The evaluation and monitoring should include the potential for medication errors.

Dispensation of Drugs
Medications must be prepared safely. Safe preparation procedures could include:
o Only the pharmacy compounds or admixes all sterile medications, intravenous admixtures, or other drugs except in emergencies or when not feasible (for example, when the product's stability is short).
o Whenever medications are prepared, staff uses safety materials and equipment while preparing hazardous medications.
o Wherever medications are prepared, staff uses techniques to ensure accuracy in medication preparation.
o Whenever medications are prepared, staff uses appropriate techniques to avoid contamination during medication preparation, which include, but are not limited, to the following:
- Using clean or sterile technique as appropriate;
- Maintaining clean, uncluttered, and functionally separate areas for product preparation to minimize the possibility of contamination;
- Using a laminar airflow hood or other appropriate environment while preparing any intravenous (IV) admixture in the pharmacy, any sterile product made from non-sterile ingredients, or any sterile product that will not be used with 24 hours; and
- Visually inspecting the integrity of the medications.

Drug Storage
All drugs and biologicals must be kept in a locked room or container. If the container is mobile or readily portable, when not in use, it must be stored in a locked room, monitored location, or secured location that will ensure the security of the drugs or biologicals.

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All drugs and biologicals must be stored in a manner to prevent access by unauthorized individuals. Persons without legal access to drugs and biologicals cannot have unmonitored access to drugs or biologicals.

Persons without legal access to drugs or biologicals cannot have keys to medication storage rooms, carts, cabinets, or containers. Whenever persons without legal access to the drugs or biologicals have unmonitored access to or could gain access to the drugs or biologicals stored in an area, the CAH would not be considered as in compliance with the requirement to store all drugs and biologicals in a locked storage area.

Nursing Medication Carts, Anesthesia Carts, Crash Carts, and Other Medication Carts
When not in use, nursing medication carts, anesthesia carts, crash carts and other medication carts (hereafter referred to as "carts") containing drugs or biologicals must be locked or stored in a locked storage room. When carts are not in use, locked carts that contain drugs or biologicals must be stored in a locked room, monitored area, or secure location. If a cart containing drugs or biologicals is in use and unlocked, someone with legal access to the drugs and biologicals in the cart must be close by and directly monitoring the cart. That person could be a nurse, a physician, or other individual who in accordance with state and federal law and CAH policy has legal access to the drugs and biologicals in the cart. That person must monitor the cart and be aware of other people's activities near the cart. He/she is responsible for the security of the drugs and biologicals in the cart.

A crash cart with a break-away lock is considered to be in a monitored area and meets the requirement for secure location.

System for Labeling and Management of Outdated Drugs
The CAH must have a pharmacy labeling, inspection, and inventory management system that ensures that outdated, mislabeled, or otherwise unusable drugs and biologicals are not available for patient use.

Survey Procedures
o Interview the chief pharmacist or the individual delegated to fulfill the chief pharmacist's functions. Determine that either the medical staff has developed policies and procedures regarding the management of pharmaceuticals or that this function is fulfilled by the pharmacy service.
o Is the staff familiar with the medication-related policies and procedures?
o Is there a method to periodically review and evaluate the actual implementation of pharmaceutical policies and procedures by staff?
o Upon review of a patient clinical record, are issues with regard to provision of pharmaceutical services identified? Is the facility aware of the issues? Was there a failure to implement a policy and procedure?

o Determine whether the pharmacist is a full-time or part-time employee or employed on a consultative basis.
o Review the implementation of the chief pharmacist's responsibilities by:
- Reviewing written status reports;
- Reviewing minutes of meetings (if any) with facility staff regarding pharmaceutical services;
- Reviewing schedules, time logs, etc.; and
- Reviewing the job description or the written agreement to see that the responsibilities of the pharmacist are clearly defined and include development, supervision, and coordination of all the activities of pharmacy services.
o Determine whether the pharmacy director is actively involved in those committees responsible for establishing medication-related policies and procedures.
o Determine that the pharmaceutical services staff is sufficient in number and training to provide quality services, including 24 hour, 7-day emergency coverage, or there is an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff. Review any agreements.
o Determine if there are sufficient personnel to provide accurate and timely medication delivery, ensure accurate and safe medication administration and to provide appropriate clinical services as well as the participation in continuous quality improvement programs that meet the needs of the patient population being served.
o Determine if there is a record system in place that provides information on controlled substances in a readily retrievable manner.
o Determine that the pharmacist is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled.
o Determine if there is a system, delineated in policies and procedures, that tracks movement of all scheduled drugs from the point of entry into the CAH to the point of departure either through administration to the patient, destruction of the drug, or return to the manufacture. Determine if this system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.
o Review the records to determine that they trace the movement of scheduled drugs throughout the service.
o Determine if the pharmacist is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and periodically reconciled.
o Is the CAH system capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual losses or diversion to the time of detection and determination of the extent of loss or diversion?
o Determine if facility policy and procedures minimize scheduled drug diversion.
o Is access to concentrated solutions (e.g. potassium chloride, sodium chloride solutions greater than 0.9%) restricted?
o Identify and assess the quality assurance procedures for the preparation of sterile products.
o Is appropriate monitoring of medication therapy being conducted?
o Is the pharmacy involved in the evaluation, use and monitoring of drug delivery systems, administration devices and

automated drug dispensing machines? The evaluation and monitoring should include the potential for medication errors.
o Review the procedures established to prevent unauthorized usage and distribution. These procedures must provide for an accounting of the receipt and disposition of drugs subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970.
o Determine that only pharmacists or pharmacy supervised personnel compound, label and dispense drugs or biologicals in accordance with State and Federal laws and regulations and as accepted national principles by:
- Reviewing policies and procedures;
- Interviewing pharmacy and CAH staff to determine how drugs and biologicals are dispensed;
- Observing on-site dispensing operations;
- Reviewing records of drugs and biologicals removed from the pharmacy by non-pharmacy personnel; and
- Inspecting drug storage areas.
o Verify through interviews of pharmacy and CAH staff, observation of on-site dispensing operations and review of pharmacy records that compounding, dispensing and packaging of drugs and biologicals are performed under the supervision of a pharmacist, in accordance with applicable laws.
o Determine that there is a policy for the safeguarding, transferring and availability of keys to the locked storage area.
o Determine by inspection whether all medications are stored in a manner that prevents unauthorized access.
o Determine if the facility identifies what personnel may have access to medications.
o Spot-check the labels of individual drug containers to verify that they conform to State laws, and/or contain the following minimal information:
- Each patient's individual drug container bears his/her full name, the prescriber's name, and strength and quantity of the drug dispensed. Appropriate accessory and cautionary statements are included as well as the expiration date.
- Each floor stock container bears the name and strength of the drug, lot and control number of equivalent, and expiration date.
o If the unit dose system is utilized, verify that each single unit dose package bears name and strength of the drug, lot and control number equivalent, and expiration date.
o Inspect patient-specific and floor stock medications to identify expired, mislabeled or unusable medications.
o Determine through pharmacy records that when the pharmacist is not available, drugs are removed from the pharmacy (drug storage area) only by a designated individual (in accordance with State law if applicable) and only in amounts sufficient for immediate therapeutic needs.
o Review policies and procedures to determine who is designated to remove drugs and biologicals from the pharmacy or storage area and the amount a non-pharmacist may remove in the absence of a pharmacist. The individual(s) designated should be identified by name and qualifications.
o Determine that a system is in place that accurately documents the removal of medications (type and quantity) from either the pharmacy or the after hours supply.

o Determine that the pharmacist reviews all medication removal activity and correlates the removal with current medication orders in the patient medication profile.
o Determine if the pharmacist routinely reviews the contents of the after-hours supply to determine if it is adequate to meet the after-hours needs of the CAH.
o Conduct a spot check of drug use and other inventory records to ensure that drugs are properly accounted for.
o Review reports of pharmaceutical services to determine if there are reported problems with controlled drugs and what actions have been taken to correct the situation.
o Interview the Pharmacy Director, pharmacist and pharmacy employees to determine their understanding of the controlled drug policies. Is there a policy and procedure for handling controlled drug discrepancies?
o Determine if controlled drug losses were reported to appropriate authorities in accordance with State and Federal laws.

FED - C0277 - PATIENT CARE POLICIES

Title PATIENT CARE POLICIES

CFR 485.635(a)(3)(v)

Type Standard

Regulation Definition

[The policies include the following:]

(v) procedures for reporting adverse drug reactions and errors in the administration of drugs.

Interpretive Guideline

Written procedures should require that medication errors and adverse drug reactions be reported immediately to the practitioner who ordered the drug. An entry, including the medication administered and the drug reaction, should be entered into the patient's medical record. Unexpected or significant adverse drug reactions should also be reported to the Food and Drug Administration in accordance with the MedWatch program. There must be a process to report serious adverse drug reactions to the FDA in accordance with the MedWatch program.

It is important to flag new types of mistakes as they occur and create systems to prevent their recurrences. The system should work through those mistakes and continually improve and refine things, based on what went wrong.

Reduction of medication errors and adverse reactions can be achieved by effective reporting systems that proactively identify causative factors and are used to implement corrective actions to reduce or prevent reoccurrences. To facilitate reporting, the facility should adopt a medication error and adverse drug reaction (ADR) definition that is broad enough in scope to capture "near misses" and suspected ADRs as well as actual medication errors and ADRs.

For high risk medications and high-risk patients (pediatric, geriatric or patients with renal or hepatic impairment) there should be systems in place to minimize adverse drug events. Such systems could include but not limited to: checklists, dose limits, pre-printed orders, special packaging, special labeling, double-checks and written guidelines.

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One example of a definition is the National Coordinating Council Medication Error Reporting and Prevention definition of a medication error.

"Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use."

In addition to broad scope definitions, the facility must also proactively identify medication errors and adverse drug reactions. Reliance solely on incident reporting fails to identify the majority of adverse drug events. Proactive identification includes observation of medications passes, concurrent and retrospective review of patient's clinical records, ADR surveillance team, implementation of medication usage evaluations for high-alert drugs and identification of indicator drugs or "patient signals" that, when ordered, or noted automatically generate a drug regimen review for a potential adverse drug event.

The facility must have a method by which to measure the effectiveness of its reporting system so as to identify whether or not its system(s) is identifying as many medication errors and adverse drug reactions that would be expected for the size and scope of services provided by their CAH. Such methods could include use of established benchmarks or studies on reporting rates published in peer-reviewed journals.

To improve incident reporting the facility should adopt a non-punitive system with the focus on the system and not the involved health care professionals.

The facility should have immediately available sufficient texts and other resources on drug therapy. The pharmacist also should be readily available by telephone or other means to discuss drug therapy, interactions, side effects, dosage etc., with practitioners to assist in drug selection and with nursing personnel to assist in the identification of drug-induced problems.

The CAH should have policies and procedures to actively identify potential and actual adverse drug events. Proactive identification could include:
o Direct observation of medication administration;
o Review of patient's clinical records; and
o Identification of patient signals that would warrant immediate review of patient's medication therapy and

implementation of medication use evaluation studies.

The CAH should have a means to incorporate external alerts and/or recommendations from national associations and governmental agencies for review and facility policy and procedure revision consideration. National associations could include Institute for Safe Medications Practice, National Coordination Council for Medication Error Reporting and Prevention and Joint Commission for Accreditation of Health Care Facilities, Sentinel Event Reports. Governmental agencies may include; Food and Drug Administration, Med Watch Program, and Agency for Health Care Research and Quality.

Provision of pharmaceutical services must meet the needs of the patients' therapeutic goal by promoting a safe medication use process that ensures optimal selection of medications, dose, dosage form, frequency, route, duration of therapy and that substantially reduces or eliminates adverse drug events and duplication of treatment.

The CAH pharmacy must ensure that drug orders are accurate and that medications are administered as ordered. When medications are returned unused, the pharmacy should determine the reason the medication was not used. For example, did the patient refuse the medication, was there a clinical reason the medication was not used, was the medication not used due to error?

Policies and procedures to minimize drug errors should include:
o High-alert medications with dosing limits, administration guidelines, packaging, labeling and storage;
o Limiting the variety of medication-related devices and equipment. For example, limit the types of general-purpose infusion pumps to one or two;
o Availability of up-to-date medication information;
o Availability of pharmacy expertise such as having a pharmacist available on-call when pharmacy does not operate 24 hours a day;
o Standardization of prescribing and communication practices;
o Avoidance of certain abbreviations;
o All elements of the order such as dose, strength, units (metric), route, frequency, and rate;
o Alert systems for look-alike and sound-alike drug names;
o Use of facility approved pre-printed order sheets whenever possible;
o A voluntary, non-punitive, reporting system to monitor and report adverse drug events (including medication errors and adverse drug reactions);
o The preparation, distribution, administration and proper disposal of hazardous medications;
o Medication recalls;
o Policies and procedures are reviewed and amended secondary to facility-generated reports of adverse drug events.

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Survey Procedures
o Examine the sources of drug information available at the nursing station and/or drug storage area and determine if they are current.
o Determine whether staff development programs on drug therapy are available to facility staff to cover such topics as new drugs added to the formulary, how to resolve drug therapy problems, and other general information as the need arises.
o Review the pharmaceutical policies and procedures, the CAH's formulary and, if there is a pharmacy and therapeutics committee, the minutes of the committee meetings.
o Verify that the purpose of pharmaceutical policies and procedures is to minimize drug errors.
o Are there policies and procedures to minimize drug errors?
o Are policies and procedures reviewed and amended secondary to facility-generated reports of adverse drug events?
o Determine that the CAH has an effective procedure that ensures drug administration errors, adverse drug reactions, and drug incompatibilities are immediately reported to the attending physician.
o Review records of medication errors and adverse drug reactions to determine that they are reported immediately in accordance with written procedures, and that medications administered and/or drug reactions are promptly recorded in the patient's medical record.
o Determine if the facility's definition of an adverse drug reaction and medication error will generate sufficient number of reports.
o Review QA activities for medication errors and adverse reaction reports to determine if upon analyses of the reports that potential corrective actions are identified and implemented, if appropriate.
o Determine if the number of medication errors and adverse drug reactions reported is consistent with the size and scope of services provided by the CAH.
o Interview facility staff (nursing, pharmacy and medicine) to ascertain awareness of the facilities policy on reporting and documentation of medication errors and adverse drug reactions.
o Is there a process to report serious adverse drug reactions to the Federal MedWatch program?

FED - C0278 - PATIENT CARE POLICIES

Title PATIENT CARE POLICIES

CFR 485.635(a)(3)(vi)

Type Standard

Regulation Definition

[The policies include the following:]

Interpretive Guideline

The CAH must have an active surveillance program that includes specific measures for prevention, early detection, control, education, and investigation of infections and communicable diseases in the CAH. There must be a

Aspen Federal Regulation Set: C 04.02 CRITICAL ACCESS HOSPITALS

(vi) a system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel.

mechanism to evaluate the effectiveness of the program and to provide corrective action when necessary. The program must include implementation of nationally recognized systems of infection control guidelines to avoid sources and transmission of infections and communicable diseases as recommended by organizations such as the Centers for Disease Control and Prevention (CDC) Guidelines for Prevention and Control of Nosocomial Infections, the CDC Guidelines for Preventing the Transmission of Tuberculosis in Health Care Facilities, the Occupational Health and Safety Administration (OSHA) regulations, and the Association for Professionals in Infection Control and Epidemiology (APIC) infection control guidelines, etc.).

The active infection control program should have policies that address the following:
o Definition of nosocomial infections and communicable diseases;
o Measures for identifying, investigating, and reporting nosocomial infections and communicable diseases;
o Measures for assessing and identifying patients and health care workers, including CAH personnel, contract staff (e.g., agency nurses, housekeeping staff), and volunteers, at risk for infections and communicable diseases;
o Methods for obtaining reports of infections and communicable diseases on inpatients and health care workers, including all CAH personnel, contract such as agency nurses, housekeeping staff, and volunteers, in a timely manner;
o Measures for the prevention of infections, especially infections caused by organisms that are antibiotic resistant or in other ways epidemiologically important; device-related infections (e.g., those associated with intravascular devices, ventilators, tube feeding, indwelling urinary catheters, etc.); surgical site infections; and those infections associated with tracheostomy care, respiratory therapy, burns, immunosuppressed patients, and other factors which compromise a patient's resistance to infection;
o Measures for prevention of communicable disease outbreaks, especially tuberculosis;
o Provision of a safe environment consistent with nationally recognized infection control precautions, such as the current CDC recommendations for the identified infection and/or communicable disease;
o Isolation procedures and requirements for infected or immunosuppressed patients;
o Use and techniques for standard precautions;
o Education of patients, family members and caregivers about infections and communicable diseases;
o Methods for monitoring and evaluating practices of asepsis;
o Techniques for hand washing, respiratory protections, asepsis, sterilization, disinfection, food sanitation, housekeeping, fabric care, liquid and solid waste disposal, needle disposal, separation of clean from dirty, as well as other means for limiting the spread of contagion;
o Authority and indications for obtaining microbiological cultures from patients;
o A requirement that disinfectants, antiseptics, and germicides be used in accordance with the manufacturers' instructions to avoid harming patients, particularly central nervous system effects on children;
o Orientation of all new CAH personnel to infections, communicable diseases, and to the infection control program;
o Measures for the screening and evaluation of health care workers, including all CAH staff, contract workers such as

agency nurses, housekeeping staff, and volunteers, for communicable diseases, and for the evaluation of staff and volunteers exposed to patients with non-treated communicable diseases;
o Employee health policies regarding infectious diseases and when infected or ill employees, including contract workers and volunteers, must not render patient care and/or must not report to work;
o A procedure for meeting the reporting requirements of the local health authority;
o Procedures for working with local, State, and Federal health authorities in emergency preparedness situations;
o Policies and procedures developed in coordination with Federal, State, and local emergency preparedness and health authorities to address communicable disease threats and outbreaks; and
o Provision for program evaluation and revision of the program, when indicated.

Designated Infection Control Officer
The CAH must designate in writing an individual or group of individuals, qualified through education, training, experience, and certification or licensure, as an infection control officer or officers.

An infection control committee may delegate responsibility for infection functions, in accordance with CAH policy.

The infection control officer or officers must develop and implement policies governing the control of infections and communicable diseases.

The infection control officer(s) is responsible for:
o Implementing policies governing asepsis and infection control;
o Developing a system for identifying, investigating, reporting, and preventing the spread of infections and communicable diseases among patients and CAH personnel, including contract staff and volunteers;
o Identifying, investigating and reporting infections and outbreaks of communicable diseases among patients and CAH personnel, including contract staff and volunteers, especially those occurring in clusters;
o Preventing and controlling the spread of infections and communicable diseases among patients and staff;
o Cooperating with CAH-wide orientation and inservice education programs;
o Cooperating with other departments and services in the performance of quality assurance activities; and
o Cooperating with disease control activities of the local health authority.

It is recommended that the infection control officer or officers maintain a log of all incidents related to infections and communicable diseases, including those identified through employee health services. The log is not limited to nosocomial infections. All incidents of infection and communicable disease should be included in the log. The log documents infections and communicable diseases of patients and all staff (patient care, non patient care, employees, contract staff and volunteers).

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The chief executive officer (CEO), the medical staff and the director of nursing (DON) must ensure that the CAH-wide Quality Assurance (QA) program and staff inservice training programs address problems identified through the infection control program.

The CEO, the medical staff, and the DON are responsible for implementing corrective action plans to address problems identified by the infection control officer(s). These plans should be evaluated for effectiveness and revised if needed, and documentation concerning corrective actions and outcomes should be maintained.

Survey Procedures
o Verify that there is a system (policies) for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and CAH personnel, including contract workers and volunteers.
o Determine that this system is an active program, that it is both CAH-wide and program-specific, and that it is implemented correctly.
o Throughout the CAH, observe the environment of care, noting the cleanliness of horizontal surfaces, bedside equipment, and air inlets, etc, because infectious organisms may spread from these places.
o Verify that an infection control officer (or officers) is designated and has the responsibility for the infection control program.
o Review the personnel file of the infection control officer(s) to verify that he/she is qualified through education, training, experience, and certification or licensure to oversee the infection control program.
o Verify that appropriate policies and procedures have been developed and implemented governing the control of infections and communicable diseases.
o Determine that the infection control officer(s) is responsible for the elements specified in the interpretive guidelines.
o Verify that the infection control officer(s) maintains a log of all incidents related to infections and communicable diseases, including those identified through employee health services.
o Determine that the CAH's QA program and staff inservice training programs address problems identified by the infection control officer(s).
o Determine that problems identified are reported to the medical staff, nursing, and administration, and addressed in the CAH's quality assurance and inservice training programs.

FED - C0279 - PATIENT CARE POLICIES

Title PATIENT CARE POLICIES

CFR 485.635(a)(3)(vii)

Type Standard

Aspen Federal Regulation Set: C 04.02 CRITICAL ACCESS HOSPITALS

Regulation Definition

[The policies include the following:]

(vii) If the CAH furnishes inpatient services, procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices and the orders of the practitioner responsible for the care of the patients, and that the requirement of §485.25(i) is met with respect to inpatients receiving posthospital SNF care.

Interpretive Guideline

A CAH is not required to prepare meals itself and is free to obtain meals under contract with another supplier, but the CAH is responsible for the quality of arranged services on the same basis as if CAH employees had provided those services.

The food and dietetic services must be organized, directed and staffed in such a manner to ensure that the nutritional needs of the patients are met in accordance with practitioners' orders and recognized dietary practices.

Policies and Procedures for Dietary Services
The CAH should have written policies and procedures that address at least the following:
o Availability of a diet manual and therapeutic diet menus to meet patients' nutritional needs;
o Frequency of meals served;
o System for diet ordering and patient tray delivery;
o Accommodation of non-routine occurrences such as enteral nutrition (tube feeding), total parenteral nutrition, peripheral parenteral nutrition, change in diet orders, early/late trays, nutritional supplements, etc.;
o Integration of the food and dietetic service into the CAH-wide QA and Infection Control programs;
o Guidelines for acceptable hygiene practices of food service personnel; and
o Guidelines for kitchen sanitation.

Compliance with Recognized Dietary Practices
The CAH must be in compliance with Federal and State licensure requirements for food and dietary personnel as well as food service standards, laws and regulations.

Director of Food and Dietetic Services
The CAH must have an employee (either on staff or contracted) who-
o Serves as director of the food and dietetic services;
o Is responsible for daily management of the dietary services; and
o Is qualified by experience or training.

The service director may be either an employee on staff or under contract, who has been granted the authority and delegated responsibility by the CAH's governing body and medical staff for the operation of the dietary services. This authority and delegated responsibility includes the daily management of the service, implementing training programs for dietary staff, and ensuring that established policies and procedures are maintained that address at least the following:
o Safety practices for food handling;
o Emergency food supplies;

o Orientation, work assignments, supervision of work and personnel performance;
o Menu planning, purchasing of foods and supplies, and retention of essential records such as cost, menus, personnel, training records, QA reports, etc.; and
o Dietary service QA program.

Additionally, the service director must demonstrate, through education, experience and/or specialized training, the qualifications necessary to manage the service, appropriate to the scope and complexity of the food service operation.

Qualified Dietitian
A qualified dietitian must supervise the nutritional aspects of patient care. The dietitian can be part of the CAH, work under contract, may be full or part time, and is responsible for all inpatient nutrition including swing bed services. The dietitian must be licensed if required by State law. The dietitian's responsibilities include, but are not limited to:
o Approving patient menus and nutritional supplements;
o Patient, family, and caretaker dietary counseling;
o Performing and documenting nutritional assessments and evaluating patient tolerance to therapeutic diets when appropriate;
o Collaborating with other CAH services (e.g., medical staff, nursing services, pharmacy service, social work service, etc.) to plan and implement patient care as necessary in meeting the nutritional needs of the patients; and
o Maintaining pertinent patient data necessary to recommend, prescribe, or modify therapeutic diets as needed to meet the nutritional needs of the patients.

If the qualified dietitian does not work full-time, and when the dietitian is not available, the CAH must make adequate provisions for dietary consultation that meets the needs of the patients. The frequency of consultation depends on the total number of patients, their nutritional needs and the number of patients requiring therapeutic diets or other nutritional supplementation.

Dietary Support Staff
There must be administrative and technical personnel competent in their respective duties.

This competency is demonstrated through education, experience and specialized training appropriate to the task(s) assigned. Personnel files should include documentation that each staff member is competent in their respective duties.

Recognized Dietary Practices

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Nutritional needs must be met in accordance with recognized dietary practices and in accordance with orders of the practitioner responsible for the care of the patients.

Recognized dietary practices include following current national standards for recommended dietary allowances such as the current Recommended Dietary Allowances (RDA) or the Dietary Reference Intake (DRI) of the Food and Nutrition Board of the National Research Council.

Menus provided by the CAH must be nutritionally balanced and meet the needs of the patients. In order to ensure that the CAH is meeting the nutritional needs of its patients, screening criteria should be developed to identify patients at nutritional risk. If a patient is identified as an altered nutritional status, a nutritional assessment should be performed on the patient. In addition to the initial nutritional assessment, the patient should be re-evaluated as necessary to ensure their ongoing nutritional needs are met. Examples of patients who may require a nutritional assessment include:
o All patients requiring artificial nutrition by any means (i.e., enteral nutrition (tube feeding), total parenteral nutrition, or peripheral parenteral nutrition);
o Patients whose medical condition, surgical intervention, or physical status interferes with their ability to ingest, digest or absorb nutrients;
o Patients whose diagnosis or presenting signs/symptoms indicates a compromised nutritional status (e.g., anorexia nervosa, bulimia, electrolyte imbalances, dysphagia, malabsorption, end stage organ diseases, etc.); and
o Patients whose medical condition can be adversely affected by their nutritional intake (e.g., diabetes, congestive heart failure, patients taking certain medications, renal diseases, etc.).

Therapeutic diets must be prescribed by the practitioner responsible for the care of the patient. Therapeutic diets should be:
o Prescribed in writing by a qualified practitioner;
o Documented in the patient's medical record including information about the patient's tolerance to the therapeutic diet as ordered; and
o Evaluated for nutritional adequacy.

A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing, and food service personnel.

Survey Procedures
o Review CAH personnel files to determine that staff is qualified based on education, experience, specialized training, and, if required by State law, is licensed, certified, or registered by the State.

Aspen Federal Regulation Set: C 04.02 CRITICAL ACCESS HOSPITALS

o If the dietitian is part-time, determine that the number of hours spent working is appropriate to serve the nutritional needs of the patients, and that the CAH makes adequate provisions for qualified consultant coverage when the dietitian is not available.
o Review personnel files for administrative and technical staff to determine if they have appropriate credentials as required and have received adequate training and are competent in their respective duties.
o Ask the CAH to show you what national standard they are following in its menus to meet the nutritional needs of their patients.
o Review patient records to verify that diet orders are provided as prescribed by the practitioner responsible for the care of the patient.
o From the sample patient records, identify patients with special nutritional needs to determine:
- If their nutritional needs have been met;
- If appropriate therapeutic diets have been ordered; and
- If their dietary intake and nutritional status is being monitored, as appropriate.

o Verify that therapeutic diet orders are prescribed and authenticated by the practitioner(s) responsible for the care of the patient.
o Determine that the therapeutic diet manual is current and:
- Has been approved by both the medical staff and a qualified dietitian;
- Is readily available to MD/DOs, nursing and food service personnel;
- Is in accordance with the current national standards, such as RDA or DRI;
- Includes the different types of therapeutic diets routinely ordered at the CAH; and
- Is consistently used as guidance for ordering and preparing patient diets.

FED - C0280 - PATIENT CARE POLICIES

Title PATIENT CARE POLICIES

CFR 485.635(a)(4)

Type Standard

Regulation Definition

These policies are reviewed at least annually by the group of professional personnel required under paragraph (a)(2) of this section, and reviewed as necessary by the CAH.

Interpretive Guideline

Survey Procedures
Review the meeting notes and policy and procedure books to verify that the patient care policies are reviewed on an annual basis by the professional group.

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FED - C0281 - DIRECT SERVICES

Title DIRECT SERVICES

CFR 485.635(b)(1)

Type Standard

Regulation Definition

General The CAH staff furnishes, as direct services, those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at another entry point into the health care delivery system, such as a low intensity hospital outpatient department or emergency department. These direct services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.

Interpretive Guideline

The CAH must provide outpatient and emergency room services as direct services at the CAH campus through the use of CAH personnel. The CAH can choose the level of services to be offered. They may offer only the basic services required by this CoP and State law or they may offer a more complex range of services. However, all the outpatient and emergency services offered must be provided at the CAH campus as direct services.

Outpatient Services are a required direct service of the CAH. All outpatient services that the CAH provides to its patients must meet the needs of the patients, in accordance with acceptable standards of practice. The CAH must provide adequate services, equipment, staff, and facilities adequate to provide the outpatient services for the scope of practices appropriate to the scope and complexity of services offered. The outpatient services may be offered at specific times. The CAH is not required to offer outpatient services 24/7 except for emergency room services.

Acceptable standards of practice include standards that are set forth in Federal or State laws, regulations or guidelines, as well as standards and recommendations promoted by nationally recognized professional organizations such as the American Medical Association, American College of Radiology, American College of Surgeons, etc.

The CAH's outpatient services must be integrated with inpatient services (e.g., medical records, radiology, laboratory, surgical services, anesthesia services, other diagnostic services, etc), as appropriate to the outpatient services offered. The CAH must have written policies in place to ensure the integration of outpatient services, including an established method of communication between outpatient service departments to corresponding inpatient services.

The outpatient services department must be accountable to a single individual who directs the overall operation of the department. The CAH should define in writing the qualifications and competencies necessary to direct the outpatient services. Qualifications include, necessary education, experience and specialized training, consistent with State law, and acceptable standards of practice.

Adequate types and numbers of qualified professional and nonprofessional personnel must be available to provide patients with the appropriate level of care and services offered by the CAH's outpatient department. The types and numbers of qualified personnel are based on the scope and complexity of outpatient services offered and the number

and types of patients treated as outpatients.

Rehabilitation Services
Rehabilitation services are optional CAH services and can include physical therapy, occupational therapy, audiology, and/or speech pathology services. If a CAH provides any degree of rehabilitative services to its patients, either directly or under arrangement, either inpatient or outpatient, the services must be organized and staffed to ensure the health and safety of patients. This includes providing rehabilitative services in accordance with practitioner orders and acceptable standards of practice.

Acceptable standards of practice include any standards that are set forth in Federal or State laws, regulations or guidelines, as well as standards and recommendations promoted by nationally recognized professional organizations such as the American Physical Therapy Association, American Speech and Hearing Association, American Occupational Therapy Association, American College of Physicians, and the American Medical Association etc.

If rehabilitative services are provided, the CAH must provide, or ensure, the appropriate equipment and types and numbers of qualified personnel necessary to furnish the rehabilitation services offered by the CAH in accordance with acceptable standards of practice.

The scope of rehabilitation services offered by the CAH, both directly or under contract, should be defined in written policies and procedures and approved by the Medical staff.

Each service, whether provided directly or through a contract, must function with established lines of authority and responsibility to ensure the health and safety of patients. There must be an adequate number of qualified staff available when needed to evaluate each patient, initiate the plan of treatment, and supervise supportive personnel when they furnish rehabilitation services. The number of qualified staff is based on the type of patients treated and the frequency, duration, and complexity of the treatment required.

The rehabilitation service must be accountable to an individual that directs the overall operation of the service. The director of the services must demonstrate through education, experience, and/or specialized training that he/she has the necessary knowledge, experience and capabilities to properly supervise and administer the service. The director may be part-time, full-time, and/or under contract. If part-time, the time spent directing the service should be appropriate with the scope of services provided.

The medical staff must define in writing the required qualifications and competencies for rehabilitation staff in each program or service offered. Qualifications should include the necessary education, experience, specialized training,

and if applicable, licensure requirements appropriate for assigned responsibilities consistent with State law.

At least one qualified professional, of the applicable discipline, must be on site when needed to:
o Perform an initial evaluation of each patient for whom rehabilitative services were ordered;
o Initiate the plan of treatment based on the initial evaluation, input from family/caregivers and in accordance with the orders of the practitioner responsible for the care of the patient; and
o Supervise supportive personnel when they furnish services.

Each patient must have an individualized plan of treatment, based on the patient's specific rehabilitation needs, input from family/caregivers and therapeutic treatment goals, that are established in writing prior to the initiation of treatment. At a minimum, the treatment plan must:
o Be established by the practitioner ordering the service in collaboration with an individual qualified to provide the services;
o Be based on the patient's individualized assessment;
o Include the type, amount, frequency and duration of services;
o Include measurable short-term and long-term goals;
o Incorporate patient, family and caregiver goals; and
o Be reviewed and revised as necessary to reflect changes in the patient's response to therapeutic intervention. Updated treatment goals should reflect the changes in the patient's status.

Changes to the treatment plan must be documented in writing and supported by clinical record information such as evaluation, test results, interdisciplinary staff conferences or MD/DO orders.

The activities described in the written plan of treatment must be within the scope of practice, State licensure, or certifications of the individual performing the activity.

Survey Procedures
o Determine the types of outpatient services provided.
o Verify that equipment, staff and facilities are adequate to provide the outpatient services and are in accordance with acceptable standards of practice.
o Verify that the outpatient services are organized in a manner appropriate to the scope and complexity of services offered.
o Verify that the CAH has an established method of communication and established procedures to assure integration with inpatient services to provide continuity of care.
o Review medical records of outpatients who were later admitted to the CAH in order to determine that pertinent

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information from the outpatient record has been included in the inpatient record.
o Determine that the outpatient services are integrated with the appropriate CAH inpatient services in accordance with the needs of the patient care provided.
o Verify that one person is assigned by the governing body (or responsible individual) to manage and be responsible for outpatient services.
o Review the position description and personnel file of the individual responsible for the outpatient services to ensure that he/she meets the qualifications, in accordance with State law, acceptable standards of practice and CAH policy.
o Review personnel files to verify that the staff qualifications, including education, experience, certifications, current licensure, where appropriate, and competencies are appropriate for assigned responsibilities.
o Verify that sufficient staff is available to provide care.
o Verify that the types and number of qualified personnel are appropriate for the types and numbers of patients receiving care and the complexity of services offered.
o Determine if the CAH provides any degree of rehabilitation services.
o Review the CAH's policies and procedures to verify that the scope of rehabilitation services offered, either directly or under contract, is defined in writing.
o Review personnel files or contracts to verify current licensure, certifications and training of staff consistent with applicable State laws.
o Determine that adequate types and numbers of qualified staff are available to ensure safe and efficient provision of treatment.
o Review medical records to verify that a qualified professional evaluates the patient and initiates the treatment under medical orders and direction for each episode.
o Verify that each patient has a plan of treatment established in writing and that the plan is established by the practitioner ordering the service and is documented in the patient record along with treatment outcomes achieved.
o If the director of the service does not work full-time, determine that the number of hours spent working is appropriate to the scope of services provided.
o Interview the director to determine if he/she has the necessary knowledge, experience and capabilities to properly supervise and administer the service.

FED - C0282 - DIRECT SERVICES

Title DIRECT SERVICES

CFR 485.635(b)(2)

Type Standard

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Regulation Definition

Laboratory services. The CAH provides, as direct services, basic laboratory services essential to the immediate diagnosis and treatment of the patient that meet the standards imposed under section 353 of the Public Health Service Act (42 U.S.C. 236a). (See the laboratory requirements specified in part 493 of this chapter.) The services provided include:
(i) Chemical examination of urine by stick or tablet method or both (including urine ketones);
(ii) Hemoglobin or hematocrit;
(iii) Blood glucose;
(iv) Examination of stool specimens for occult blood;
(v) Pregnancy tests; and
(vi) Primary culturing for transmittal to a certified laboratory.

Interpretive Guideline

Basic laboratory services must be provided directly at the CAH campus by CAH staff in order to facilitate the immediate diagnosis and treatment of the patient. The CAH must have a current Clinical Laboratory Improvement Act (CLIA) certificate or waiver for all tests performed.

The provision of laboratory services that exceed the requirements for basic laboratory services is an optional requirement. The CAH must maintain or have available laboratory services, either directly or through arrangement, whenever its patients need those services. The CAH may maintain laboratory services at the CAH or may make laboratory services available through contractual agreements except for the required basic services. The scope and complexity of the CAH laboratory service must be adequate to meet the needs of its patients. All laboratory services, whether direct or contractual must be provided in accordance with CLIA requirements. Every CAH laboratory must be operating under a current CLIA certificate (including a waiver certificate) appropriate to the level of services performed.

The CAH must provide basic emergency laboratory services 24 hours a day, 7 days a week. The medical staff should determine which laboratory services are to be immediately available to meet the emergency laboratory needs of patients who may be currently at the CAH or those patients who may arrive at the CAH in an emergency condition and how the services are to be provided. The emergency laboratory services available should reflect the scope and complexity of the CAH's operation and be provided in accordance with Federal and State law, regulations and guidelines and acceptable standards of practice.

The laboratory must have written instructions for the collection, preservation, transportation, receipt, and reporting of tissue specimen results.

Survey Procedures
o Determine which services are provided directly by the facility and which are provided through contractual agreements.
o Determine if the referral laboratory is CLIA certified for the appropriate test specialty.
o Verify that all laboratory services are operating under a current CLIA certificate.
o Examine records and determine if the services, including emergency services, are provided in accordance with the CAH'S policies.
o Review the written description of the emergency laboratory services.
o Review records such as worksheets and test reports to verify the 24 hour availability of emergency services and that those services are provided when required.
o Verify the existence of a written description of the laboratory services provided, including those furnished on routine and stat basis (either directly or under an arrangement with an outside facility). Verify that the description of

services is accurate and current.
o Verify that the CAH has a procedure in place for obtaining tests that are needed but unavailable at the CAH laboratory.
o Verify that the CAH has written policies and procedures to ensure that all laboratory results are recorded in the medical record.

FED - C0283 - DIRECT SERVICES

Title DIRECT SERVICES

CFR 485.635(b)(3)

Type Standard

Regulation Definition

Radiology services. Radiology services furnished at the CAH are provided as direct services by staff qualified under State law, and do not expose CAH patients or staff to radiation hazards.

Interpretive Guideline

Radiological services must be provided by the CAH as direct services at the CAH campus by CAH staff. The CAH must maintain and have available diagnostic radiological services to meet the needs of their patients. These services must be available at all times. The CAH can choose the level of services offered. They may offer only a minimal set of services or a more complex range of services (including nuclear medicine) according to the needs of the patients of the CAH. While the CAH must directly provide all radiology services in the CAH, the interpretation of roentgenograms may be contracted out.

All radiological services provided by the CAH, including diagnostic, therapeutic, and nuclear medicine, must be provided in accordance with acceptable standards of practice and must meet professionally approved standards for safety. The scope and complexity of radiological services offered should be specified in writing and approved by the medical staff and governing body (or responsible individual) of the CAH.

Acceptable standards of practice include maintaining compliance with appropriate Federal and State laws, regulations and guidelines governing radiological services, including facility licensure and/or certification requirements, as well as any standards and recommendations promoted by nationally recognized professions such as the American Medical Association, American College of Radiology, etc.

The CAH must adopt policies and procedures that provide safety for patients and personnel. The CAH must implement and ensure compliance with its established safety standards. The policies should contain safety standards for at least:
o Adequate radiation shielding for patients, personnel and facilities;
o Labeling of radioactive materials, waste, and hazardous areas;
o Transportation of radioactive materials between locations within the CAH;

o Security of radioactive materials, including determining who may have access to radioactive materials and controlling access to radioactive materials;
o Testing of equipment for radiation hazards;
o Maintenance of personal radiation monitoring devices;
o Storage of radio nuclides and radio pharmaceuticals as well as radioactive waste; and
o Disposal of radio nuclides, unused radio pharmaceuticals, and radioactive waste.

The CAH must have policies and procedures in place to ensure that periodic inspections of radiology equipment are conducted, and that problems identified are corrected in a timely manner. The CAH must have a system in place and qualified employees to correct hazards. The CAH must be able to demonstrate current inspection and proper correction of all hazards.

There must be written policies developed and approved by the medical staff to designate which radiological tests must be interpreted by a radiologist.

Supervision of the radiology services includes, but is not limited, to the following:
o Enforcing safety standards;
o Ensuring that radiology reports are signed by the practitioner who interpreted them;
o Assigning duties to radiology personnel appropriate to their level of training, experience, and licensure if applicable;
o Enforcing infection control standards;
o Ensuring that emergency care is provided to patients who experience an adverse reaction to diagnostic agents in the radiology service;
o Ensuring that files, scans, and other image records are kept in a secure area and are readily retrievable; and
o Training radiology staff on how to operate the equipment safely, perform tests offered by the facility and on the management of emergency radiation hazards and accidents.

There should be written policies, developed and approved by the medical staff, consistent with State law, to designate which personnel are qualified to use the radiological equipment and administer procedures.

The CAH must maintain records for all radiology procedures performed. At a minimum, the records should include copies of reports and printouts, and any films, scans or other image records, as appropriate. The CAH should have written policies and procedures that ensure the integrity of authentication and protect the privacy of radiology records.

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Survey Procedures
o Verify that the CAH maintains, or has available, organized radiology services that meet the needs of the patients, are provided in accordance with accepted standards of practice, and are maintained or available at all times to meet the patient needs.
o Verify that patient shielding (aprons, etc.) are properly maintained and routinely inspected.
o Verify that the CAH requires periodic tests of all radiology personnel and that the personnel are knowledgeable about radiation exposure.
o Review records to verify that periodic tests of radiology personnel by exposure meters or test badges are performed.
o Verify that hazardous materials are stored properly in a safe manner.
o Review the inspection records (logs) to verify that periodic inspections are conducted in accordance with manufacturer's instructions, Federal and State laws, regulations, and guidelines, and CAH policy.
o Determine that any problems identified are properly corrected in a timely manner.
o Review medical records to determine that radiological services are provided only on the orders of practitioners with clinical privileges authorized by the medical staff and the governing body (or responsible individual) to order radiological services, consistent with State law.
o Review records to determine that a radiologist interprets those tests that have been designated by the medical staff to require interpretation by a qualified radiologist.
o Verify that supervision of the radiology services is restricted to an individual who is credentialed by the medical staff.
o Review radiological records to determine that reports are signed by the practitioner who reads and evaluates the roentgenogram.
o Verify through observation and document review that radioactive materials, including radioactive waste, are properly stored and disposed of.
o Verify that the CAH maintains accurate records of the receipt and distribution of radio pharmaceuticals.

FED - C0284 - DIRECT SERVICES

Title DIRECT SERVICES

CFR 485.635(b)(4)

Type Standard

Regulation Definition	**Interpretive Guideline**
Emergency procedures. In accordance with the requirements of §485.618, the CAH provides as direct services medical emergency procedures as a first response to common life-threatening injuries and acute illness.	Survey Procedures Review policies and procedures for the provision of emergency services.

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FED - C0285 - SERVICES PROVIDED THRU AGREEMENT/ARRANGEMENT

Title SERVICES PROVIDED THRU AGREEMENT/ARRANGEMENT
CFR 485.635(c)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients including --	Individual agreements or arrangements should be well defined, but need not be contractual. They should describe routine procedures (e.g., for obtaining outside laboratory tests); and there should be evidence in the agreement or arrangement that the governing body (or responsible individual) is responsible for these services provided under agreement or arrangement. Individual agreements or arrangements should be revised when the nature and scope of services provided has changed. The governing body (or responsible individual) has the responsibility for ensuring that CAH services are provided according to acceptable standards of practice, irrespective of whether the services are provided directly by CAH employees or indirectly by arrangement. The governing body must take actions through the CAH's QA program to: assess the services furnished directly by CAH staff and those services provided under arrangement, identify quality and performance problems, implement appropriate corrective or improvement activities, and to ensure the monitoring and sustainability of those corrective or improvement activities. Survey Procedures Ascertain that all contractor services provided in the CAH are in compliance with the CoPs for CAHs.

FED - C0286 - SERVICES PROVIDED THRU AGREEMENT/ARRANGEMENT

Title SERVICES PROVIDED THRU AGREEMENT/ARRANGEMENT
CFR 485.635(c)(1)(i)

Type Standard

Regulation Definition	Interpretive Guideline
[The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including--]	Survey Procedures How does the CAH ensure that it has arrangements or agreements with one or more facilities to provide inpatient care to its patients?

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(i) inpatient hospital care

FED - C0287 - SERVICES PROVIDED THRU AGREEMENT/ARRANGEMENT

Title SERVICES PROVIDED THRU AGREEMENT/ARRANGEMENT
CFR 485.635(c)(1)(ii)

Type Standard

Regulation Definition	Interpretive Guideline
[The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including--]	Survey Procedures How does the CAH ensure that it has arrangements or agreements with one or more MD/DOs to meet its requirements at §485.631(b)?
(ii) services of doctors of medicine or osteopathy; [and]	

FED - C0288 - SERVICES PROVIDED THRU AGREEMENT/ARRANGEMENT

Title SERVICES PROVIDED THRU AGREEMENT/ARRANGEMENT
CFR 485.635(c)(1)(iii)

Type Standard

Regulation Definition	Interpretive Guideline
[The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including-]	Laboratories that provide additional diagnostic and clinical laboratory services to a CAH by agreement or arrangement must be in compliance with CLIA requirements in 42 CFR Part 493 of this chapter. These laboratories will be surveyed separately for compliance with Part 493.
(iii) additional or specialized diagnostic and clinical laboratory services that are not available at the CAH.	Survey Procedures How does the CAH ensure through arrangements or agreements that it can obtain specialized diagnostic and clinical laboratory services?

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FED - C0289 - SERVICES PROVIDED THRU AGREEMENT/ARRANGEMENT

Title SERVICES PROVIDED THRU AGREEMENT/ARRANGEMENT
CFR 485.635(c)(1)(iv)

Type Standard

Regulation Definition

[The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including--]

(iv) food and other services to meet inpatients' nutritional needs to the extent these services are not provided directly by the CAH.

Interpretive Guideline

Survey Procedures
If the CAH has an outside contract for nutritional services, how does the CAH ensure that it has arrangements or agreements for the provision of nutritional services that meet this requirement?

FED - C0290 - SERVICES PROVIDED THRU AGREEMENT/ARRANGEMENT

Title SERVICES PROVIDED THRU AGREEMENT/ARRANGEMENT
CFR 485.635(c)(2)

Type Standard

Regulation Definition

If the agreements or arrangements are not in writing, the CAH is able to present evidence that patients referred by the CAH are being accepted and treated.

Interpretive Guideline

Survey Procedures
Review a sample of medical records of patients who were treated and transferred from the CAH. What documentation shows that:
o Transferred patients were accepted and provided with inpatient care, as needed, at CAHs to which they were transferred?
o Patients referred for diagnostic and/or laboratory tests had these tests performed as requested by the practitioner responsible for the patient?
o MD/DOs and/or suppliers of services are providing services for the CAH in the manner described in the arrangement or agreement?

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FED - C0291 - SERVICES PROVIDED THRU AGREEMENT/ARRANGEMENT

Title SERVICES PROVIDED THRU AGREEMENT/ARRANGEMENT
CFR 485.635(c)(3)

Type Standard

Regulation Definition	Interpretive Guideline
The CAH maintains a list of all services furnished under arrangements or agreements. The list describes the nature and scope of the services provided.	Survey Procedures o Review the list of contracted services and verify that there is a delineation of contractor responsibility. o Review any arrangements or agreements to determine if the nature and scope of services defined is being provided to CAH patients and is in compliance with the CAH CoPs.

FED - C0292 - SERVICES PROVIDED THRU AGREEMENT/ARRANGEMENT

Title SERVICES PROVIDED THRU AGREEMENT/ARRANGEMENT
CFR 485.635(c)(4)(i)

Type Standard

Regulation Definition	Interpretive Guideline
The person principally responsible for the operation of the CAH under §485.627(b)(2) of this chapter is also responsible for the following: (i) services furnished in the CAH whether or not they are furnished under arrangements or agreements.	Survey Procedures How does the CAH ensure, (e.g., through operating policies and procedures, by-laws etc.) that the individual responsible for its operations is responsible for all services provided through arrangements or agreements?

FED - C0293 - SERVICES PROVIDED THRU AGREEMENT/ARRANGEMENT

Title SERVICES PROVIDED THRU AGREEMENT/ARRANGEMENT
CFR 485.635(c)(4)(ii)

Type Standard

Aspen Federal Regulation Set: C 04.02 CRITICAL ACCESS HOSPITALS

Regulation Definition	Interpretive Guideline
[The person principally responsible for the operation of the CAH under §485.627(b)(2) of this chapter is also responsible for the following:]	Survey Procedures How does the CAH ensure that contracted services meet all of the CAH Conditions of Participation and standards for contracted services?
(ii) ensuring that a contractor of services (including one for shared services and joint ventures) furnishes services that enable the CAH to comply with all applicable conditions of participation and standards for the contracted services.	

FED - C0294 - NURSING SERVICES

Title NURSING SERVICES

CFR 485.635(d)

Type Standard

Regulation Definition	Interpretive Guideline
Nursing services must meet the needs of patients.	In order to meet the needs of patients, nursing services must be a well-organized service of the CAH and under the direction of a registered nurse. The CAH and the director of the nursing service are responsible for the clinical activities of all nursing to include the clinical activities of all non-CAH nursing personnel (contract, agency, or volunteer). The CAH and the director of nursing service ensure that all CAH nursing staff and each non-CAH nursing staff person is adequately trained and oriented, is adequately supervised, that their clinical activities are evaluated, and that all nursing personnel know the CAH policies and procedures. An appropriately qualified CAH-employed RN should conduct the supervision and evaluation of the clinical activities of each non-CAH nursing staff. Survey Procedures o Observe the nursing care in progress to determine the adequacy of staffing and to assess the delivery of care. Other sources of information to use in the evaluation of the nursing services are: nursing care plans, medical records, accident and investigative reports, staffing schedules, nursing policies and procedures, credentialing and training files (including contracted staff), and QA activities and reports. o Review the method for orienting non-CAH staff to CAH policies and procedures. The orientation should include at least the following:

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- The CAH and the unit;
- Emergency procedures;
- Nursing services policies and procedures; and
- Safety policies and procedures.

FED - C0295 - NURSING SERVICES

Title NURSING SERVICES

CFR 485.635(d)(1)

Type Standard

Regulation Definition

A registered nurse must provide (or assign to other personnel) the nursing care of each patient, including patients at a SNF level of care in a swing-bed CAH. The care must be provided in accordance with the patient's needs and the specialized qualifications and competence of the staff available.

Interpretive Guideline

The nursing service ensures that patient needs are met by ongoing assessments of patients' needs and provides nursing staff to meet those needs. There must be sufficient personnel to respond to the appropriate medical needs and care of the patient population being serviced.

An RN must make all patient care assignments. The director of the nursing service and the CAH are to ensure that nursing personnel with the appropriate education, experience, licensure, competence and specialized qualifications are assigned to provide nursing care for each patient in accordance with the individual needs of each patient.

Survey Procedures
o Review the nursing assignments. Did an RN make the assignments? Determine that the assignments take into consideration the complexity of patient care needs and the competence and specialized qualifications of the nursing staff.
o Determine that there are written staffing schedules that correlate to the number and acuity of patients.
o Verify that there is supervision of personnel performance and nursing care for each nursing unit.
o Interview the registered nurse responsible for supervising the nursing care of the patients and ask the following:
- How are the specialized needs of patients determined? Who makes this determination?
- How is staff assigned?
- How is staff monitored to ensure that appropriately qualified staff provides the care needed?
- How does the CAH ensure that care provided meets the needs of each patient?
- If temporary nursing staff is utilized, how are these staff oriented and supervised relative to CAH nursing procedures?
o Interview one or more temporary staff, if available, to determine if they are adequately familiar with CAH nursing requirements.

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FED - C0296 - NURSING SERVICES

Title NURSING SERVICES

CFR 485.635(d)(2)

Type Standard

Regulation Definition	Interpretive Guideline
A registered nurse or, where permitted by State law, a physician assistant, must supervise and evaluate the nursing care for each patient, including patients at a SNF level of care in a swing-bed CAH.	An RN (or PA where State law permits) must supervise and evaluate the nursing care for each patient. Evaluation would include assessing the patient's care needs as well as the patient's response to interventions. Survey Procedures o Determine that a registered nurse (or PA where State law permits) supervises and evaluates the nursing care for each patient? o Interview the RN (or PA where State law permits) who is responsible for supervising and evaluating the nursing care for CAH patients. o Ask to see staffing schedules as needed to verify information. o Observe the care provided by any non-CAH staff. - Do they know and adhere to CAH policies? - Do they know appropriate emergency procedures? - Are they adequately supervised by an appropriately experienced CAH employed RN (or PA where State law permits)? - Are their clinical activities being evaluated adequately? - Are they licensed in accordance with State law? o Confirm with the director of nurses that a non-CAH nurse's performance is evaluated at least annually.

FED - C0297 - NURSING SERVICES

Title NURSING SERVICES

CFR 485.635(d)(3)

Type Standard

Regulation Definition	Interpretive Guideline
All drugs, biologicals, and intravenous medications must be	All drugs and biologicals and intravenous medications must be administered by or under the supervision of a RN,

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administered by or under the supervision of a registered nurse, a doctor of medicine or osteopathy, or where permitted by State law, a physician assistant, in accordance with written and signed orders, accepted standards of practice, and Federal and State laws.

MD, DO or PA where permitted by State law, in accordance with written or signed orders, accepted standards of practice, and Federal and State laws. As permitted by State law and CAH policy, LPN's may administer medications if they are under the supervision of an RN, MD, DO or PA if permitted by State law..

Drugs and biologicals must be prepared and administered in accordance with Federal and State laws.

Drugs and biologicals must be prepared and administered in accordance with the orders of the practitioner or practitioners responsible for the patient's care.

Drugs and biologicals must be prepared and administered in accordance with accepted standards of practice.

All orders for drugs and biologicals, including verbal orders, must be legible, timed, dated and authenticated with a signature by the practitioner or practitioners responsible for the care of the patient. All entries in the medical record must be legible, timed, dated and authenticated.

A telephone or verbal order is written in the medical record by a nurse or other professional in accordance with State law and CAH policy as being able to accept verbal orders. The written verbal order must be legible and includes the date, time, the order, the name of the ordering practitioner and the signature of the accepting individual. The ordering practitioner must date and time the order at the time he or she signs the order and must sign a verbal order as soon as possible which would be the earlier of the following:
o The next time the prescribing practitioner provides care to the patient, assesses the patient, or documents information in the patient's medical record, or
o The prescribing practitioner signs or initials the verbal order within time frames consistent with Federal and State law or regulation and CAH policy.

The content of verbal orders should be clearly communicated. The entire verbal order should be repeated back to the prescriber. All verbal orders must be reduced immediately to writing and signed by the individual receiving the order. Verbal orders must be documented in the patient's medical record, and be reviewed and countersigned by the prescriber as soon as possible.

We recognize that in some instances, the ordering practitioner may not be able to authenticate his or her verbal order (e.g., the ordering practitioner gives a verbal order which is written and transcribed, and then is "off duty" for the weekend or an extended period of time). In such cases, it is acceptable for a covering practitioner to co-sign the verbal order of the ordering practitioner. The signature indicates that the covering practitioner assumes responsibility for his/her colleague's order as being complete, accurate and final. This practice must be addressed in the CAH's

policy. However, a qualified practitioner such as a physician assistant or nurse practitioner may not "co-sign" a MD/DO's verbal order or otherwise authenticate a medical record entry for the MD/DO who gave the verbal order.

When used, verbal orders must be used infrequently. Therefore, it is not acceptable to allow covering practitioners to authenticate verbal orders for convenience or to make this common practice. When assessing compliance with this requirement, surveyors review the frequency and practice of using verbal orders within the CAH.

Verbal orders are orders for medications, treatments, intervention or other patient care that are communicated as oral, spoken communications between senders and receivers face to face or by telephone.

Verbal communication of orders should be limited to urgent situations where immediate written or electronic communication is not feasible.

CAHs should establish policies and procedures that:
o Describe limitations or prohibitions on use of verbal orders;
o Provide a mechanism to ensure validity/authenticity of the prescriber;
o List the elements required for inclusion in a complete verbal order;
o Describe situations in which verbal orders may be used;
o List and define the individuals who may send and receive verbal orders; and
o Provide guidelines for clear and effective communication of verbal orders.

CAHs should promote a culture in which it is acceptable, and strongly encouraged, for staff to question prescribers when there are any questions or disagreements about verbal orders. Questions about verbal orders should be resolved prior to the preparation, or dispensing, or administration of the medication.

Elements that should be included in any verbal medication order include:
o Name of patient;
o Age and weight of patient, when appropriate;
o Date and time of the order;
o Drug name;
o Dosage form (e.g., tablets, capsules, inhalants)
o Exact strength or concentration;
o Dose, frequency, and route;
o Quantity and/or duration;
o Purpose or indication;

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o Specific instructions for use; and
o Name of prescriber.

Survey Procedures
o Select patients from the patient sample. Review their medication orders, medication administration records, and appropriate medication documentation in the medical record. Observe the preparation and administration of medications to those patients. Are medications prepared and administered in accordance with Federal and State laws, accepted national standards of practice, manufacturer's directions, and CAH policy?
o Ascertain that there is an effective method for the administration of drugs. Use the following indicators for assessing drug administration.
o Ascertain that there are policies and procedures approved by the medical staff covering who is authorized to administer medications, and that the policies are followed.
o Review a sample of medication administration records to see that they conform to the practitioner's order and that the order is current, and that drug and dosage are correct and administered as ordered.
o Observe the preparation of drugs and their administration to patients in order to verify that procedures are being followed. Are patients addressed by name and/or identiband checked? Does the nurse remain with the patient until medication is taken?
o Verify that nursing staff administering drugs has completed appropriate training courses.
o Check the QA activities to see if the administration of drugs is regularly monitored. The monitoring should include reports of medication irregularities or errors and corrective action taken.
o Determine that all drug orders, including verbal orders, are written in the patient charts and signed by the practitioner caring for the patient. Have verbal orders been signed or initialed by the prescribing practitioner as soon as possible?
o Request to see several patient charts with telephone orders. Check to determine if they are taken by authorized CAH personnel, and are correctly countersigned by the practitioner. Ask several nurses if they are permitted to take telephone and oral orders and how frequently they do so.
o Read the CAH's policy for practitioner's orders. Does it require that orders must be in writing and signed by the attending practitioner?
o Verify that the prescriber has reviewed and authenticated the orders in accordance with medical staff policy and/or applicable State laws.

FED - C0298 - NURSING SERVICES

Title NURSING SERVICES

CFR 485.635(d)(4)

Type Standard

Aspen Federal Regulation Set: C 04.02 CRITICAL ACCESS HOSPITALS

Regulation Definition	Interpretive Guideline
A nursing care plan must be developed and kept current for each inpatient.	Nursing care planning starts upon admission. It includes planning the patient's care while in the CAH as well as planning for discharge to meet post-CAH needs. A nursing care plan is based on assessing the patient's nursing care needs and developing appropriate nursing interventions in response to those needs. The nursing care plan is kept current by ongoing assessments of the patient's needs and the patient's response to interventions, and updating or revising the patient's nursing care plan in response to assessments. The nursing care plan is part of the patient's medical record and must comply with the requirements for patient records. Survey Procedures Select a sample of nursing care plans (6-12 as appropriate) o Are the plans initiated as soon as possible after admission for each patient? o Does the plan describe patient goals and appropriate physiological and psychosocial factors and patient discharge planning? o Is the plan consistent with the attending practitioner's plan for medical care? o Are the plans revised as the needs of the patient change? o Are the plans implemented?

FED - C0300 - CLINICAL RECORDS

Title CLINICAL RECORDS

CFR 485.638

Type Condition

Regulation Definition	Interpretive Guideline
Clinical Records	Yhe CAH must ensure that the clinical record requirements are met.

FED - C0301 - RECORDS SYSTEMS

Title RECORDS SYSTEMS

CFR 485.638(a)(1)

Type Standard

Aspen Federal Regulation Set: C 04.02 CRITICAL ACCESS HOSPITALS

Regulation Definition	Interpretive Guideline
The CAH maintains a clinical records system in accordance with written policies and procedures.	The CAH must have a system of patient records, pertinent medical information, author identification, and record maintenance that ensures the integrity of the authentication and protects the security of all record entries. The medical record system must correctly identify the author of every medical record entry. The medical record system must protect the security of all medical record entries. The medical record system must ensure that medical record entries are not lost, stolen, destroyed, altered, or reproduced in an unauthorized manner. All locations where medical records are stored or maintained must ensure the integrity, security and protection of the records. The CAH must have a system in place that ensures that the identity of the author of each entry is correct. The author of every entry must take a specified action to identify himself/herself as the author (or responsible person) of the entry, the time and dating of the entry, that the entry is accurate, and that he/she takes responsibility for accuracy of the entry. If the CAH uses computer entries there must be security system in place to ensure the integrity of the record system, to ensure that the author of each entry is correctly identified, to ensure that record entries are not altered or lost, that limits access to medical records to only authorized persons, and ensures that records are not released to unauthorized individuals. For the purposes of this regulation, electronic signatures comply with those medical record entries that include a requirements for a signature. There should be a current list of authenticated signatures, as well as a list of computer codes and signature stamps (when used for authorship purposes) that have been authorized by the governing body and are protected by adequate safeguards. CAH policies and procedures should provide for appropriate sanctions for unauthorized or improper use of computer codes or signature stamps. The CAH must maintain a medical record for each inpatient and outpatient evaluated or treated in any part or location of the CAH. A unit record for both inpatients and outpatients may be used; however, when two different systems are used they must be appropriately cross referenced. When a patient reimbursement status changes from acute care services to swing bed services, a single medical record may be used for both stays as long as the record is sectioned separately. Both sections must include admission and discharge orders, progress notes, nursing notes, graphics, laboratory support documents, any other pertinent documents, and discharge summaries. The medical record must be properly filed and retained. The CAH must have a medical recording system that ensures the prompt retrieval of any medical record, of any patient evaluated or treated at any location of the CAH within the past 6 years. The medical record must be accessible. The CAH must have a medical record system that allows the medical record

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of any patient, inpatient or outpatient, evaluated and/or treated at any location of the CAH within the past 6 years to be accessible by appropriate staff, 24 hours a day, 7 days a week, whenever that medical record may be needed.

Survey Procedures
o Verify that a medical record is maintained for each person receiving care.
o Verify that written procedures ensure the integrity of authentication and protect the security of patient records.
o Verify that medical records are stored and maintained in locations where the records are secure, with protection from damage, flood, fire, theft, etc., and limits access to only authorized individuals.
o Verify that records are accurate, completed promptly, easily retrieved and readily accessible, as needed.
o Verify that there is an established system that addresses at least the following activities of the medical records services:
- Timely processing and retrieval of records;
- Protecting the confidentiality of medical information;
- Compiling and retrieval of data of quality assurance activities.
o Verify that the system policies and procedures are reviewed and revised as needed.
o Verify that the CAH employs adequate medical record personnel who possess adequate education, skills, qualifications and experience to ensure the CAH complies with requirements of the medical records regulations and other appropriate Federal and State laws and regulations.
o Are medical records promptly completed in accordance with State law and CAH policy?
o Select a sample of past patients of the CAH (inpatient and/or outpatient). Request those patient's medical records. Can the CAH promptly retrieve those records?

FED - C0302 - RECORDS SYSTEMS

Title RECORDS SYSTEMS

CFR 485.638(a)(2)

Type Standard

Regulation Definition

The records are legible, complete, accurately documented, readily accessible, and systematically organized.

Interpretive Guideline

All medical records must be accurately written. The CAH must ensure that all medical records accurately and completely document all orders, test results, evaluations, treatments, interventions, care provided and the patient's response to those treatments, interventions and care.

Survey Procedures
For CAH surveys that are conducted after the initial certification survey, examine a sample of records using an adequate sample size to evaluate the scope of services provided. In a very small CAH, look at all inpatient and

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outpatients records, if appropriate.

FED - C0303 - RECORDS SYSTEMS

Title RECORDS SYSTEMS

CFR 485.638(a)(3)

Type Standard

Regulation Definition	Interpretive Guideline
A designated member of the professional staff is responsible for maintaining the records and for ensuring that they are completely and accurately documented, readily accessible, and systematically organized.	The CAH must have one unified medical record service with a department head that has been appointed by the governing body (or responsible individual). The director of medical records must have responsibility for all medical records to include both inpatient and outpatient records. Survey Procedures o Verify that the CAH employs adequate medical record personnel. o Review the organizational structure and policy statements and interview the person responsible for the service to ascertain that the medical records service is structured appropriately to meet the needs of the CAH and the patients.

FED - C0304 - RECORDS SYSTEMS

Title RECORDS SYSTEMS

CFR 485.638(a)(4)(i)

Type Standard

Regulation Definition	Interpretive Guideline
For each patient receiving health care services, the CAH maintains a record that includes, as applicable- (i) identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;	The medical record must include evidence of properly executed informed consent forms for any procedures or surgical procedures specified by the medical staff, or by Federal or State law, if applicable, that require written patient consent. Informed consent means the patient or patient representative is given the information, explanations, consequences, and options needed in order to consent to a procedure or treatment. A properly executed consent form contains at least the following: o Name of patient, and when appropriate, patient's legal guardian;

o Name of CAH;
o Name of procedure(s);
o Name of practitioner(s) performing the procedures(s);
o Signature of patient or legal guardian;
o Date and time consent is obtained;
o Statement that procedure was explained to patient or guardian;
o Signature of professional person witnessing the consent;
o Name/signature of person who explained the procedure to the patient or guardian.

The medical record must contain information such as progress and nursing notes, documentation, records, reports, recordings, test results, assessments etc. to:
o Justify admission;
o Support the diagnosis;
o Describe the patient's progress;
o Describe the patient's response to medications; and
o Describe the patient's response to services such as interventions, care, treatments, etc.

The medical record must contain complete information/documentation regarding medical history, assessment of the health status and health care needs of the patient, and a summary of the episode, disposition, and instructions to the patient. This information and documentation is contained in a discharge summary.

A discharge summary discusses the outcome of the CAH stay, the disposition of the patient, and provisions for follow-up care. Follow-up care provisions include any post CAH appointment, how post CAH patient care needs are to be met, and any plans for post-CAH care by providers such as swing-bed services, home health, hospice, nursing homes, or assisted living. A discharge summary is required following any CAH acute care stay prior to and following a swing-bed admission and discharge.

The MD/DO or other qualified practitioner with admitting privileges in accordance with State law and CAH policy, who admitted the patient is responsible for the patient during the patient's stay in the CAH. This responsibility would include developing and entering the discharge summary.

The MD/DO may delegate writing the discharge summary to other qualified health care personnel such as nurse practitioners and physician assistants to the extent recognized under State law or a State's regulatory mechanism. The MD/DO may also delegate writing the discharge summary to another MD/DO who is familiar with the patient.

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Survey Procedures
o Verify that the medical staff have specified which procedures or treatments require a written informed consent.
o Verify that medical records contain consent forms for all procedures or treatment that are required by CAH policy.
o Verify that consent forms are properly executed.
o Examine a sample of patient records and/or facility records of requests for information contained in patient records to determine if there are signed and dated consent forms, when required, medical history, health status and care needs assessment, and discharge summary in each record, as needed.
o Review of sample of active and closed medical records for completeness and accuracy in accordance with Federal and State laws and regulations and CAH policy. The sample should be at least 10 percent of the average daily census, as appropriate.

FED - C0305 - RECORDS SYSTEMS

Title RECORDS SYSTEMS

CFR 485.638(a)(4)(ii)

Type Standard

Regulation Definition

[For each patient receiving health care services, the CAH maintains a record that includes, as applicable-]

(ii) reports of physical examinations, diagnostic and laboratory test results, including clinical laboratory services, and consultative findings;

Interpretive Guideline

All or part of the history and physical exam (H & P) may be delegated to other practitioners in accordance with State law and CAH policy, but the MD/DO must sign the H & P and assume full responsibility for the H & P. This means that a nurse practitioner or a physician assistant meeting these criteria may perform the H & P.

Survey Procedures
o Determine that the bylaws require a physical examination and medical history be done for each patient.
o For sampled records, does the appropriate practitioner sign reports of physical examinations, diagnostic and laboratory test results, and consultative findings?

FED - C0306 - RECORDS SYSTEMS

Title RECORDS SYSTEMS

CFR 485.638(a)(4)(iii)

Type Standard

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Regulation Definition	Interpretive Guideline
[For each patient receiving health care services, the CAH maintains a record that includes, as applicable-]	The requirement means that the stated information is necessary to monitor the patient's condition and that this and other necessary information must be in the patient's medical record. In order for necessary information to be used it must be promptly filed in the medical record so that health care staff involved in the patient's care can access/retrieve this information in order to monitor the patient's condition and provide appropriate care.
(iii) all orders of doctors of medicine or osteopathy or other practitioners, reports of treatments and medications, nursing notes and documentation of complications, and other pertinent information necessary to monitor the patient's progress, such as temperature graphics and progress notes describing the patient's response to treatments; [and]	The medical record must contain: o All practitioner's orders (properly authenticated); o All nursing notes; o All reports of treatment (including complications and CAH-acquired infections); o All medication records (including unfavorable reactions to drugs); o All radiology reports; o All laboratory reports; o All vital signs; and o All other information necessary to monitor the patient's condition. All medical records must be promptly completed. Every medical record must be complete with all documentation of orders, diagnosis, evaluations, treatments, test results, consents, interventions, discharge summary, and care provided along with the patient's response to those treatments, interventions, and care. Survey Procedures o Verify that the patient records contain appropriate documentation of practitioners' orders, interventions, findings, assessments, records, notes, reports and other information necessary to monitor the patient's condition. o Is necessary information included in patient records in a prompt manner so that health care staff involved in the care of the patient have access to the information necessary to monitor the patient's condition?

FED - C0307 - RECORDS SYSTEMS

Title RECORDS SYSTEMS

CFR 485.638(a)(4)(iv)

Type Standard

Regulation Definition	Interpretive Guideline
[For each patient receiving health care services, the CAH	Entries in the medical record may be made only by individuals as specified in CAH and medical staff policies. All

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maintains a record that includes, as applicable-]

(iv) dated signatures of the doctor of medicine or osteopathy or other health care professional.

entries in the medical record must be timed, dated, and authenticated, and a method established to identify the author. The identification may include written signatures, initials, computer key, or other code.

When rubber stamps are authorized, the individual whose signature the stamp represents shall place in the administrative offices of the CAH a signed statement to the effect that he/she is the only one who has the stamp and uses it. There shall be no delegation to another individual.

A list of computer or other codes and written signatures must be readily available and maintained under adequate safeguards. There shall be sanctions for improper or unauthorized use of stamp, computer key, or other code signatures. The CAH must have policies and procedures in place and operational before an electronic medical record system would be deemed acceptable.

The parts of the medical record that are the responsibility of the MD/DO must be authenticated by this individual. When non-MD/DOs have been approved for such duties as taking medical histories or documenting aspects of physical examination, such information shall be appropriately authenticated by the responsible MD/DO. Any entries in the medical record by house staff or non-MD/DOs that require counter signing by supervisory or attending medical staff members shall be defined in the medical staff rules and regulations.

All entries in the medical record must be authenticated.

Authentication would include at a minimum:
o The CAH has a method to establish the identify of the author of each entry. This would include verification of the author of faxed orders/entries or computer entries.
o The author takes a specific action to verify that the entry is his/her entry or that he/she is responsible for the entry, that the entry is accurate.
o The timing of the entry is noted and correct.

Timing documents the time and date of each entry (orders, reports, notes etc.). Timing establishes when an order was given, when an activity happened or when an activity is to take place. Timing and dating entries are necessary for patient safety and quality of care. Timing and dating of entries establishes a baseline for future actions or assessments and establishes a timeline of events. Many patient interventions or assessments are based on time intervals or time lines of various signs, symptoms, or events. There must be a specific action by the author to indicate that the entry is, in fact, verified and accurate. Failure to disapprove an entry within a specific time period is not acceptable as authentication.

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A system of auto-authentication in which a MD/DO or other practitioner authenticates a report before transcription is not consistent with these requirements. There must be a method of determining that the practitioner did, in fact, authenticate the document after it was transcribed.

Survey Procedures
o Verify that entries are authenticated.
o Verify that the department maintains a current list of authenticated signatures, written initials, codes, and stamps when such are used for authorship identification.
o Verify that computer or other code signatures are authorized by the CAH's governing body and that a list of these codes is maintained under adequate safeguards by the CAH administration.
o Verify that the CAH's policies and procedures provide for appropriate sanctions for unauthorized or improper use of the computer codes.
o Examine the CAH's policies and procedures for using the system, and determine if documents are being authenticated after transcription.
o For sampled records, are there dated and authenticated signatures by appropriate MD/DOs and/or mid-level practitioners, as needed?

FED - C0308 - PROTECTION OF RECORD INFORMATION

Title PROTECTION OF RECORD INFORMATION

CFR 485.638(b)(1)

Type Standard

Regulation Definition

The CAH maintains the confidentiality of record information and provides safeguards against loss, destruction, or unauthorized use.

Interpretive Guideline

The CAH has sufficient safeguards to ensure that access to all information regarding patients is limited to those individuals designated by law, regulation, policy; or duly authorized as having a need to know. No unauthorized access or dissemination of clinical records is permitted. Clinical records are kept secure and are only viewed when necessary by those persons having a part in the patient's care.

The right to confidentiality means safeguarding the content of information, including patient paper records, video, audio, and/or computer stored information from unauthorized disclosure without the specific informed consent of the individual, parent of a minor child, or legal guardian. CAH staff and consultants, hired to provide services to the individual, should have access to only that portion of information that is necessary to provide effective responsive services to that individual.

Confidentiality applies to both central records and clinical record information that may be kept at dispersed locations.

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Survey Procedures
o Verify that only authorized persons are permitted access to records maintained by the medical records department.
o Verify that the CAH has a policy to grant patients direct access to his/her medical record if the responsible official (e.g., practitioner responsible for patient's care) determines that direct access is not likely to have an adverse effect on the patient.
o Verify that medical records are released only for patient care evaluation, utilization review, treatment, quality assurance programs, in-house educational purposes, or in accordance with Federal or State law, court orders, or subpoenas.
o Verify that copies of medical records are released outside the CAH only upon written authorization of the patient, legal guardian, or person with an appropriate "power of attorney" to act on the patient's behalf, or only if there is a properly executed subpoena or court order, or as mandated by statutes.
o Verify that precautions are taken to prevent unauthorized persons from gaining access to or altering patient records.
o Verify that adequate precautions are taken to prevent physical or electronic altering, damaging or deletion/destruction of patient records or information in patient records.

FED - C0309 - PROTECTION OF RECORD INFORMATION

Title PROTECTION OF RECORD INFORMATION

CFR 485.638(b)(2)

Type Standard

Regulation Definition

Written policies and procedures govern the use and removal of records from the CAH and the conditions for the release of information.

Interpretive Guideline

The CAH's patient record system must ensure the security of patient records. The CAH must ensure that unauthorized individuals cannot gain access to patient records and that individuals cannot alter patient records. Patient records must be secure at all times and in all locations. This includes open patient records for patients who are currently inpatients in the CAH and outpatients in outpatient clinics.

Survey Procedures
o Observe the CAH's security practices for patient records. Are patient records left unsecured or unattended? Are patient records unsecured or unattended in hallways, patient rooms, nurses stations, or on counters where an unauthorized person could gain access to patient records?
o If the CAH uses electronic patient records, are appropriate security safeguards in place? Is access to patient records controlled?
o Verify that the CAH has policies and procedures for the use and release of records and that these policies and procedures are enforced.

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FED - C0310 - PROTECTION OF RECORD INFORMATION

Title PROTECTION OF RECORD INFORMATION

CFR 485.638(b)(3)

Type Standard

Regulation Definition	Interpretive Guideline
The patient's written consent is required for release of information not required by law.	

FED - C0311 - RETENTION OF RECORDS

Title RETENTION OF RECORDS

CFR 485.638(c)

Type Standard

Regulation Definition	Interpretive Guideline
The records are retained for at least 6 years from date of last entry, and longer if required by State statute, or if the records may be needed in any pending proceeding.	Medical records are retained in their original form or legally reproduced form in hard copy, microfilm, or computer memory banks. The CAH must be able to promptly retrieve the complete medical record of every individual evaluated or treated in any part or location of the CAH within the last 6 years. In accordance with Federal and State law and regulations, certain medical records may have retention requirements that exceed 6 years (for example: FDA, OSHA, EPA). Survey Procedures Determine that records are retained for at least 6 years, or more if required by State or local laws.

FED - C0320 - SURGICAL SERVICES

Title SURGICAL SERVICES

CFR 485.639

Type Condition

Aspen Federal Regulation Set: C 04.02 CRITICAL ACCESS HOSPITALS

Regulation Definition

Surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body of the CAH in accordance with the designation requirements under paragraph (a) of this section.

Interpretive Guideline

The provision of surgical services is an optional CAH service. However, if a CAH provides any degree of surgical services to its patients, the services must be organized and staffed in such a manner to ensure the health and safety of patients. Surgical services that are performed in a safe manner would be performed in accordance with acceptable standards of practice. In accordance with acceptable standards of practice includes maintaining compliance with applicable Federal and State laws, regulations and guidelines governing surgical services or surgical service locations, as well as, any standards and recommendations promoted by or established by nationally recognized professional organizations (e.g., the American Medical Association, American College of Surgeons, Association of Operating Room Nurses, Association for Professionals in Infection Control and Epidemiology, etc.) Additionally, the quality of the CAH's outpatient surgical services must be consistent with the CAH's inpatient surgical services.

When the CAH offers surgical services, the CAH must provide the appropriate equipment and types and numbers of qualified personnel necessary to furnish the surgical services offered by the CAH in accordance with acceptable standards of practice.

The scope of surgical services provided by the CAH should be defined in writing and approved by the medical staff.

Supervision in the OR
The operating room (inpatient and outpatient) must be supervised by an experienced staff member authorized by State law. The supervisor's experience could include education, background working in surgical services, and specialized training in the provision of surgical services/management of surgical service operations. The CAH should address its required qualifications for the supervisor of the CAH's operating rooms in its policies.

If the CAH utilizes LPN or operating room technicians as "scrub nurses", those personnel must be under the supervision of an RN who is immediately available to physically intervene and provide care, as required in State law.

Policies and Procedures
Policies governing surgical care should contain:
o Aseptic surveillance and practice, including scrub techniques;
o Identification of infected and non-infected cases;
o Housekeeping requirements/procedures;
o Patient care requirements;
o Preoperative work-up;
o Patient consents and releases;
o Clinical procedures;
o Safety practices;

o Patient identification procedures;
o Duties of scrub and circulating nurse;
o Safety practices;
o The requirement to conduct surgical counts in accordance with accepted standards of practice;
o Scheduling of patients for surgery;
o Personnel policies unique to the OR;
o Resuscitative techniques;
o DNR status;;
o Care of surgical specimens;
o Malignant hyperthermia;
o Appropriate protocols for all surgical procedures performed. These may be procedure-specific or general in nature and will include a list of equipment, materials, and supplies necessary to properly carry out job assignments;
o Sterilization and disinfection procedures;
o Acceptable operating room attire; and
o Handling infections and biomedical/medical waste.

Policies and procedures must be written, implemented and enforced. Surgical services' policies must be in accordance with acceptable standards of medical practice and surgical patient care.

Pre-operative History and Physical (H & P)
A complete history and physical must be conducted in accordance with acceptable standards of practice, and the written document placed on the medical record, prior to surgery. All or part of the H & P may be delegated to other practitioners in accordance with State law and CAH policy, but the surgeon must sign the H & P and assume full responsibility for the H & P. This means that a nurse practitioner or a physician assistant, meeting these criteria, may perform the H & P.

In all circumstances, when an H & P has been conducted, but is not present on the chart prior to surgery, or in emergency situations where a complete H & P cannot be conducted prior to surgery, a brief admission note on the chart is necessary. The note should include at a minimum critical information about the patient's condition including pulmonary status, cardiovascular status, BP, vital signs, etc.

Informed Consent
A properly executed informed consent form contains at least the following:
o Name of patient, and when appropriate, patient's legal guardian;
o Name of CAH;

o Name of procedure(s);
o Name of practitioner(s) performing the procedure(s) or important aspects of the procedure(s), as well as the name(s) and specific significant surgical tasks that will be conducted by practitioners other than the primary surgeon/practitioner. (Significant surgical tasks include: opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues.);
o Signature of patient or legal guardian;
o Date and time consent is obtained;
o Statement that procedure was explained to patient or guardian;
o Signature of professional person witnessing the consent; and
o Name/signature of person who explained the procedure to the patient or guardian.

The responsible practitioner must disclose to the patient any information necessary to enable the patient to evaluate a proposed medical or surgical procedure before submitting to it. Informed consent requires that a patient have a full understanding of that to which he or she has consented. An authorization from a patient who does not understand what he/she is consenting to is not informed consent.

Patients must be given sufficient information to allow them to make intelligent choices from among the alternative courses of available treatment for their specific ailments. Informed consent must be given despite a patient's anxiety or indecisiveness.

The responsible practitioner must provide as much information about treatment options as is necessary based on a patient's personal understanding of the practitioner's explanation of the risks of treatment and the probable consequences of the treatment.

Informed consent means the patient or patient representative is given (in a language or means of communication he/she understands) the information needed in order to consent to a procedure or treatment.

An informed consent would include at least: an explanation of the nature and purpose of the proposed procedures, risks and consequences of the procedures, risks and prognosis if no treatment is rendered, the probability that the proposed procedure will be successful, and alternative methods of treatment (if any) and their associated risks and benefits. Furthermore, informed consent would include that the patient is informed as to who will actually perform surgical interventions that are planned. When practitioners other than the primary surgeon will perform important parts of the surgical procedures, even when under the primary surgeon's supervision, the patient must be informed of who these other practitioners are, as well as, what important tasks each will carry out.

Post-Operative Care/Recovery
Adequate provisions for immediate post-operative care means:
o Post operative care must be in accordance with acceptable standards of practice.
o The post-operative care area or recovery room is a separate area of the CAH. Access is limited to authorized personnel.
o Policies and procedures specify transfer requirements to and from the recovery room. Depending on the type of anesthesia and length of surgery, the post-operative check before transferring the patient from the recovery room should include some of the following:
- Level of activity;
- Respirations;
- Blood pressure;
- Level of consciousness; and
- Patient color.
o If the patients are not transferred to the recovery room, determine that provisions are made for close observation until they have regained consciousness, e.g., direct observation by an RN in the patient's room.

Operating Room Register
The register should include at least the following information:
o Patient's name;
o Patient's CAH identification number;
o Date of the operation;
o Inclusive or total time of the operation;
o Name of the surgeon and any assistant(s);
o Name of nursing personnel (scrub and circulating);
o Type of anesthesia used and name of person administering it;
o Operation performed;
o Pre and post-op diagnosis; and
o Age of patient.

Operative Report
The operative report would include at least:
o Name and CAH identification number of the patient;
o Date and times of the surgery;
o Name(s) of the surgeon(s) and assistants or other practitioners who performed surgical tasks (even when performing those tasks under supervision);

o Pre-operative and post-operative diagnosis;
o Name of the specific surgical procedure(s) performed;
o Type of anesthesia administered;
o Complications, if any;
o A description of techniques, findings, and tissues removed or altered;
o Surgeons or practitioners name(s) and a description of the specific significant surgical tasks that were conducted by practitioners other than the primary surgeon/practitioner (significant surgical procedures include: opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues); and
o Prosthetic devices, grafts, tissues, transplants, or devices implanted, if any.

Survey Procedures
o Inspect all inpatient and outpatient operative rooms/suites. Request the use of proper attire for the inspection. Observe the practices to determine if the services are provided in accordance with acceptable standards of practice. Observe:
- That access to the operative and recovery area is limited to authorized personnel and that the traffic flow pattern adheres to accepted standards of practice;
- The conformance to aseptic and sterile technique by all individuals in the surgical area;
- That there is appropriate cleaning between surgical cases and appropriate terminal cleaning applied;
- That operating room attire is suitable for the kind of surgical case performed, that persons working in the operating suite must wear only clean surgical costumes, that surgical costumes are designed for maximum skin and hair coverage;
- That equipment is available for rapid and routine sterilization of operating room materials and that equipment is monitored, inspected, tested, and maintained by the CAH's biomedical equipment program; and
- That sterilized materials are packaged, handled, labeled, and stored in a manner that ensures sterility e.g., in a moisture and dust controlled environment and policies and procedures for expiration dates have been developed and are followed in accordance with accepted standards of practice.
o Review the CAH's organizational chart displaying the relationship of the operating room service to other services. Confirm that the operating room's organization chart indicates lines of authority and delegation of responsibility within the department or service.
o If LPNs and surgical technologists (STs) are performing circulating duties, verify that they do so in accordance with applicable State laws and approved medical staff policies and procedures.
o Verify in situations where LPNs and STs are permitted to circulate that a qualified RN supervisor is immediately available to respond to emergencies.
o Review policies and procedures, to ascertain whether they contain the minimum policies specified in the interpretive guidelines.

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o Review a sample of medical records of surgical patients to determine if a complete history and physical examination by a surgeon is completed prior to surgery, except in an emergency, and in accordance with the methodology described above.
o Review a sample of medical records of surgical patients to verify that they contain consent forms. Ascertain that the completed forms contain at least the information specified in the interpretive guidelines.
o Check to determine that the operating room suite has available the items listed.
- On-call system;
- Cardiac monitor;
- Resuscitator;
- Defibrillator;
- Aspirator (suction equipment); and
- Tracheotomy set (a cricothyroidotomy set is not a substitute).

o Verify that all equipment is working and, as applicable, in compliance with the CAH's biomedical equipment inspection, testing, and maintenance program.
o Verify that the CAH has provisions for post-operative care.
o Determine that there are policies and procedures that govern the recovery room area.
o Examine the OR register or equivalent record which lists all surgery performed by the surgery service. Determine that the register includes items specified in the interpretive guidelines.
o Review a sample of medical records of patients who had a surgical encounter. Verify that they contain a surgical report that is dated and signed by the responsible surgeon and includes the information specified in the interpretive guidelines.

FED - C0321 - DESIGNATION OF QUALIFIED PRACTITIONERS

Title DESIGNATION OF QUALIFIED PRACTITIONERS

CFR 485.639(a)

Type Standard

Regulation Definition	Interpretive Guideline
The CAH designates the practitioners who are allowed to perform surgery for CAH patients, in accordance with its approved policies and procedures, and with State scope of practice laws. Surgery is performed only by	Surgical privileges should be reviewed and updated at least every 2 years. A current roster listing each practitioner's specific surgical privileges must be available in the surgical suite and area/location where the scheduling of surgical procedures is done. A current list of surgeons suspended from surgical privileges or whose surgical privileges have been restricted must be retained in these area/locations.
(1) a doctor of medicine or osteopathy, including an osteopathic practitioner recognized under section 1101(a)(7)	The CAH must delineate the surgical privileges of all practitioners performing surgery and surgical procedures. The medical staff is accountable to the governing body for the quality of care provided to patients. The medical staff

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of the Act;

(2) a doctor of dental surgery or dental medicine; or a doctor of podiatric medicine; or

(3) a doctor of podiatric medicine.

bylaws must include criteria for determining the privileges to be granted to an individual practitioner and a procedure for applying the criteria to individuals requesting privileges. Surgical privileges are granted in accordance with the competencies of each practitioner. The medical staff appraisal procedures must evaluate each individual practitioner's training, education, experience, and demonstrated competence as established by the CAH's QA program, credentialing process, the practitioner's adherence to CAH policies and procedures, and in accordance with scope of practice and other State laws and regulations.

The CAH must specify the surgical privileges for each practitioner that performs surgical tasks. This would include practitioners such as MD/DOs, dentists, oral surgeons, podiatrists, RN first assistants, nurse practitioners, surgical physician assistants, surgical technicians, etc. When a practitioner may perform certain surgical procedures under supervision, the specific tasks/procedures and the degree of supervision (to include whether or not the supervising practitioner is in the same OR in line of sight) be delineated in that practitioner's surgical privileges and included on the surgical roster.

When practitioners whose scope of practice for conducting surgical procedures requires the supervision of an MD/DO surgeon, the term "supervision" would mean the supervising MD/DO surgeon is present in the same room, working with the same patient.

Surgery and all surgical procedures must be conducted by a practitioner who meets the medical staff criteria and procedures for the privileges granted, who has been granted surgical privileges in accordance with those criteria established by the governing body (or responsible individual), and who is working within the scope of those granted and documented privileges.

Survey Procedures
o Review the CAH's method for reviewing the surgical privileges of practitioners. This method should require a written assessment of the practitioner's training, experience, health status, and performance.
o Determine that a current roster listing each practitioner's specific surgical privileges is available in the surgical suite and the area where the scheduling of surgical procedures is done.
o Determine that a current list of surgeons suspended from surgical privileges or who have restricted surgical privileges is retained in these areas/locations.

FED - C0322 - ANESTHETIC RISK & EVALUATION

Title ANESTHETIC RISK & EVALUATION

CFR 485.639(b)

Type Standard

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Regulation Definition	Interpretive Guideline
(1) A qualified practitioner, as specified in paragraph (a) of this section, must examine the patient immediately before surgery to evaluate the risk of the procedure to be performed. (2) A qualified practitioner, as specified in paragraph (c) of this section, must examine each patient before surgery to evaluate the risk of anesthesia. (3) Before discharge from the CAH, each patient must be evaluated for proper anesthesia recovery by a qualified practitioner, as specified in paragraph (c) of this section.	The evaluation for surgical risk must be performed prior to inpatient or outpatient surgery by an MD/DO; a doctor of dental surgery or dental medicine; or a doctor of podiatric medicine. The evaluation for pre-op anesthesia and post-op anesthesia recovery must be performed by an individual privileged by the CAH to administer anesthesia in accordance with §485.639(c). The pre-operative anesthetic evaluation should include: o Notation of anesthesia risk; o Anesthesia, drug and allergy history; o Any potential anesthesia problems identified; and o Patient's condition prior to induction of anesthesia. The post-anesthesia follow-up report must be written on all inpatients and outpatients prior to discharge from surgery and anesthesia services. The post-anesthesia evaluation must be written by the individual who is qualified to administer the anesthesia. An MD/DO may delegate the post-anesthesia assessment and the writing of the post-anesthesia follow-up report to practitioners qualified to administer anesthesia in accordance with State law and CAH policy. When delegation of the post-anesthesia follow-up report is permitted, the medical staff must address its delegation requirements and methods in its bylaws. The post-anesthesia follow-up report must be documented in the patient's medical record, whether the patient is an inpatient or outpatient of the CAH, and must include at a minimum: o Cardiopulmonary status; o Level of consciousness; o Any follow-up care and/or observations; and o Any complications occurring during post-anesthesia recovery. Survey Procedures o Review records to determine that each patient has a pre-anesthesia evaluation by an individual qualified to administer anesthesia. The evaluation must be performed prior to surgery. o Review medical records to determine that a post-anesthesia follow-up report is written for each patient receiving anesthesia services, by the individual who administered the anesthesia prior to discharge from anesthesia services. Documentation should include those items specified in interpretive guidelines.

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FED - C0323 - ADMINISTRATION OF ANESTHESIA

Title ADMINISTRATION OF ANESTHESIA

CFR 485.639(c)(1)

Type Standard

Regulation Definition

The CAH designates the person who is allowed to administer anesthesia to CAH patients in accordance with its approved policies and procedures and with State scope of practice laws.
(1) Anesthesia must be administered by only -
(i) a qualified anesthesiologist;
(ii) a doctor of medicine or osteopathy other than an anesthesiologist, including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;
(iii) a doctor of dental surgery or dental medicine;
(iv) a doctor of podiatric medicine;
(v) a certified registered nurse anesthetist (CRNA), as defined in Sec. 410.69(b) of this chapter;
(vi) an anesthesiologist's assistant, as defined in Sec. 410.69(b) of this chapter; or
(vii) a supervised trainee in an approved educational program, as described in §§413.85 or 413.86 of this chapter.

Interpretive Guideline

The medical staff bylaws must include criteria for determining the privileges to be granted to an individual practitioner and a procedure for applying the criteria to individuals requesting privileges. The CAH must specify the anesthesia privileges for each practitioner that administers anesthesia, or who supervises the administration of anesthesia by another practitioner. The privileges granted must be in accordance with State law and CAH policy. The type and complexity of procedures for which the practitioner may administer anesthesia, or supervise another practitioner supervising anesthesia, must be specified in the privileges granted to the individual practitioner.

A dentist, oral surgeon, or podiatrist may administer anesthesia in accordance with State law, their scope of practice and CAH policy. The anesthesia privileges of each practitioner must be specified. Anesthesia privileges are granted in accordance with the practitioner's scope of practice, State law, the individual competencies of the practitioner and the practitioner's compliance with the CAH's credentialing criteria.

When a CAH permits operating practitioners to supervise CRNA administering anesthesia, the medical staff must specify in the statement of privileges for each category of operating practitioner, the type and complexity of procedures they may supervise.
A CRNA may administer anesthesia when under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed (unless supervision is exempted in accordance with §485.639(e)). An anesthesiologist's assistant may administer anesthesia when under the supervision of an anesthesiologist who is immediately available if needed. Available to immediately intervene includes at a minimum, that the supervising anesthesiologist or operating practitioner, as applicable, is:
o Physically located within the operative suite or in the labor and delivery unit; and
o Is prepared to immediately conduct hands-on intervention if needed; and
o Is not engaged in activities that could prevent the supervising practitioner from being able to immediately intervene and conduct hands-on interventions if needed.

Survey Procedures
o Review the qualifications of individuals authorized to deliver anesthesia.
o Determine that there is documentation of current licensure or current certification status for all persons

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administering anesthesia.

FED - C0324 - ADMINISTRATION OF ANESTHESIA

Title ADMINISTRATION OF ANESTHESIA

CFR 485.639(c)(2)

Type Standard

Regulation Definition	Interpretive Guideline
(2) In those cases in which a CRNA administers the anesthesia, the anesthetist must be under the supervision of the operating practitioner except as provided in paragraph (e) of this section. An anesthesiologist's assistant who administers anesthesia must be under the supervision of an anesthesiologist.	

FED - C0325 - DISCHARGE

Title DISCHARGE

CFR 485.639(d)

Type Standard

Regulation Definition	Interpretive Guideline
All patients are discharged in the company of a responsible adult, except those exempted by the practitioner who performed the surgical procedure.	Any exceptions to this requirement must be made by the attending practitioner and annotated on the clinical record. Survey Procedures Verify that the CAH has policies and procedures in place to govern discharge procedures and instructions.

FED - C0326 - STATE EXEMPTION

Title STATE EXEMPTION

CFR 485.639(e)

Type Standard

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Regulation Definition

(1) A CAH may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (c) (2) of this section, if the State in which the CAH is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision for CRNAs. The letter from the Governor must attest that he or she has consulted with the State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws and the withdrawal of the request may be submitted at any time, and are effective upon submission.

Interpretive Guideline

FED - C0330 - PERIODIC EVALUATION & QA REVIEW

Title PERIODIC EVALUATION & QA REVIEW

CFR 485.641

Type Condition

Regulation Definition

Periodic Evaluation and Quality Assurance Review

Interpretive Guideline

While conducting the survey, a surveyor may identify a patient care practice or other CAH practice with which the surveyor is unfamiliar. Health care and CAH practice are continually changing due to new laws, regulations and standards of practice. In order for the surveyor to determine compliance with the CAH CoP, the surveyor should interview appropriate CAH staff to gather additional information, such as:
o Tell me about this practice.
o Is the practice a requirement or standard of practice?
o What is your source for this requirement, activity or standard of practice?
o Show me your source material for this practice.

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If the CAH produces a law, regulation, or standard of practice from a nationally recognized organization, evaluate whether the CAH's policies and procedures reflect the law, regulation, or standard of practice. Then, evaluate whether the CAH's actual practice reflects their policies and procedures, as well as the law, regulation or standard of practice.

FED - C0331 - PERIODIC EVALUATION

Title PERIODIC EVALUATION

CFR 485.641(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The CAH carries out or arranges for a periodic evaluation of its total program. The evaluation is done at least once a year and includes review of--	Survey Procedures o How is information obtained to be included in the periodic evaluation? o How does the CAH conduct the periodic evaluation? o Who is responsible for conducting the periodic evaluation?

FED - C0332 - PERIODIC EVALUATION

Title PERIODIC EVALUATION

CFR 485.641(a)(1)(i)

Type Standard

Regulation Definition	Interpretive Guideline
[The evaluation is done at least once a year and includes review of--] (i) the utilization of CAH services, including at least the number of patients served and the volume of services.	Survey Procedures How does the CAH ensure that the yearly program evaluation includes a review of all CAH services, the number of patients served and the volume of services provided?

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FED - C0333 - PERIODIC EVALUATION

Title PERIODIC EVALUATION

CFR 485.641(a)(1)(ii)

Type Standard

Regulation Definition	Interpretive Guideline
[The evaluation is done at least once a year and includes review of--]	"A representative sample of both active and closed clinical records" means not less than 10 percent of both active and closed patient records and both inpatient and outpatient records.
(ii) a representative sample of both active and closed clinical records.	Survey Procedures o Who is responsible for the review of both active and closed clinical records? o How are records selected and reviewed in the periodic evaluation? o How does the evaluation process ensure that the sample of records is representative of services furnished? o What criteria are utilized in the review of both active and closed records?

FED - C0334 - PERIODIC EVALUATION

Title PERIODIC EVALUATION

CFR 485.641(a)(1)(iii)

Type Standard

Regulation Definition	Interpretive Guideline
[The evaluation is done at least once a year and includes review of--]	Survey Procedures What evidence demonstrates that the health care policies of the CAH are evaluated, reviewed and/or revised as part of the annual program evaluation?
(i) the CAH's health care policies.	

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FED - C0335 - PERIODIC EVALUATION

Title PERIODIC EVALUATION

CFR 485.641(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
The purpose of the evaluation is to determine whether the utilization of services was appropriate, the established policies were followed, and any changes are needed.	Survey Procedures o How does the CAH use the results of the yearly program evaluation? o Were policies, procedures and /or facility practices added, deleted or revised as a result of the yearly program evaluation if needed?

FED - C0336 - QUALITY ASSURANCE

Title QUALITY ASSURANCE

CFR 485.641(b)

Type Standard

Regulation Definition	Interpretive Guideline
The CAH has an effective quality assurance program to evaluate the quality and appropriateness of the diagnosis and treatment furnished in the CAH and of the treatment outcomes. The program requires that -	"An effective quality assurance program" means a QA program that includes: o Ongoing monitoring and data collection; o Problem prevention, identification and data analysis; o Identification of corrective actions; o Implementation of corrective actions; o Evaluation of corrective actions; and o Measures to improve quality on a continuous basis. Survey Procedures Review a copy of the CAH QA plan and other documentation regarding QA activities, (e.g., meeting notes from QA committees, reports produced by the QA director and/or QA committees, if designated, and follow-up communication relative to corrective actions) to become familiar with the scope, methodology and organization of the CAH QA program.

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FED - C0337 - QUALITY ASSURANCE

Title QUALITY ASSURANCE

CFR 485.641(b)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The quality assurance program requires that all patient care services and other services affecting patient health and safety are evaluated.	Survey Procedures o Who is responsible to evaluate CAH patient care services? o How are patient care services evaluated? o What other services are evaluated? o How does the CAH ensure quality assurance data is provided to the medical staff and governing body?

FED - C0338 - QUALITY ASSURANCE

Title QUALITY ASSURANCE

CFR 485.641(b)(2)

Type Standard

Regulation Definition	Interpretive Guideline
[The program requires that--] nosocomial infections and medication therapy are evaluated;	Survey Procedures o What methodology does the CAH use to evaluate nosocomial infections and medications therapy? o Review committee meeting minutes for current issues or projects, etc.

FED - C0339 - QUALITY ASSURANCE

Title QUALITY ASSURANCE

CFR 485.641(b)(3)

Type Standard

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Regulation Definition	Interpretive Guideline
[The program requires that--] the quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialists, and physician assistants at the CAH are evaluated by a member of the CAH staff who is a doctor of medicine or osteopathy or by another doctor of medicine or osteopathy under contract with the CAH;	Survey Procedures o How does the CAH ensure that a doctor of medicine or osteopathy evaluates the quality of care provided by mid-level practitioners in the CAH? o How is clinical performance of mid-level practitioners evaluated? o What evidence demonstrates that there is an ongoing evaluation of care provided by mid-level practitioners (e.g., reports, periodic written evaluation, QA meeting notes)? o How does the reviewing MD/DO inform the CAH if he/she determines that there are problems relative to the diagnosis and treatment provided by mid-level practitioners? o What follow-up actions are called for in the QA plan?

FED - C0340 - QUALITY ASSURANCE

Title QUALITY ASSURANCE

CFR 485.641(b)(4)

Type Standard

Regulation Definition	Interpretive Guideline
[The program requires that--] the quality and appropriateness of the diagnosis and treatment furnished by doctors of medicine or osteopathy at the CAH are evaluated by- (i) one hospital that is a member of the network, when applicable; (ii) one QIO or equivalent entity; or (iii) one other appropriate and qualified entity identified in the State rural health care plan; and	

FED - C0341 - QUALITY ASSURANCE

Title QUALITY ASSURANCE

CFR 485.641(b)(5)(i)

Type Standard

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Regulation Definition	Interpretive Guideline
[The program requires that--] the CAH staff considers the findings of the evaluations, including any findings or recommendations of the QIO, and takes corrective action if necessary.	

FED - C0342 - QUALITY ASSURANCE

Title QUALITY ASSURANCE

CFR 485.641(b)(5)(ii)

Type Standard

Regulation Definition	Interpretive Guideline
[The program requires that--] The CAH takes appropriate remedial action to address deficiencies found through the quality assurance program.	Survey Procedures o How does the CAH ensure that proper remedial actions are taken to correct deficiencies identified in the quality assurance program? o Who is responsible for implementing remedial actions to correct deficiencies identified by the quality assurance program?

FED - C0343 - QUALITY ASSURANCE

Title QUALITY ASSURANCE

CFR 485.641(b)(5)(iii)

Type Standard

Regulation Definition	Interpretive Guideline
[The program requires that--] The CAH documents the outcome of all remedial action.	Survey Procedures How does the CAH document the outcome of any remedial action?

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FED - C0344 - ORGAN, TISSUE, EYE PROCUREMENT

Title ORGAN, TISSUE, EYE PROCUREMENT

CFR 485.643

Type Condition

Regulation Definition	Interpretive Guideline
The CAH must have and implement written protocols [with respect to organ, tissue & eye donation]	The CAH must have written policies and procedures to address its organ procurement responsibilities.

FED - C0345 - ORGAN, TISSUE, EYE PROCUREMENT

Title ORGAN, TISSUE, EYE PROCUREMENT

CFR 485.643(a)

Type Standard

Regulation Definition	Interpretive Guideline
[The CAH must have and implement written protocols that:] incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the CAH. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the CAH, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the CAH for this purpose;	The CAH must have a written agreement with an Organ Procurement Organization (OPO), designated under 42 CFR Part 486. At a minimum, the written agreement must address the following: o The criteria for referral, including the referral of all individuals whose death is imminent or who have died in the CAH; o Includes a definition of "imminent death"; o Includes a definition of "timely notification"; o Addresses the OPO's responsibility to determine medical suitability for organ donation; o Specifies how the tissue and/or eye bank will be notified about potential donors using S notification protocols developed by the OPO in consultation with the CAH-designated tissue and eye bank(s); o Provides for notification of each individual death in a timely manner to the OPO (or designated third party) in accordance with the terms of the agreement; o Ensures that the designated requestor training program offered by the OPO has been developed in cooperation with the tissue bank and eye bank designated by the CAH; o Permits the OPO, tissue bank, and eye bank access to the CAH's death record information according to a designated schedule, e.g., monthly or quarterly; o Includes that the CAH is not required to perform credentialing reviews for, or grant privileges to, members of organ

recovery teams as long as the OPO sends only "qualified, trained individuals" to perform organ recovery; and
o The interventions the CAH will utilize to maintain potential organ donor patients so that the patient organs remain viable.

CAHs must notify the OPO of every death or imminent death in the CAH. When death is imminent, the CAH must notify the OPO both before a potential donor is removed from a ventilator and while the potential donor's organs are still viable. The CAH should have a written policy, developed in coordination with the OPO and approved by the CAH's medical staff and governing body, to define "imminent death". The definition for "imminent death" should strike a balance between the needs of the OPO and the needs of the CAH's care givers to continue treatment of a patient until brain death is declared or the patient's family has made the decision to withdraw supportive measures. Collaboration between OPOs and CAHs will create a partnership that furthers donation, while respecting the perspective of CAH staff.

The definition for "imminent death" might include a patient with severe, acute brain injury who:
o Requires mechanical ventilation;
o Is in an intensive care unit (ICU) or emergency department; AND
o Has clinical findings consistent with a Glascow Coma Score that is less than or
equal to a mutually-agreed-upon threshold; or
o MD/DOs are evaluating a diagnosis of brain death; or
o An MD/DO has ordered that life sustaining therapies be withdrawn, pursuant to the family's decision.

CAHs and their OPO should develop a definition of "imminent death" that includes specific triggers for notifying the OPO about an imminent death.

In determining the appropriate threshold for the Glasgow Coma Score (GCS), it is important to remember that if the threshold is too low, there may be too many "premature" deaths or situations where there is a loss of organ viability. Standards for appropriate GCS thresholds may be obtained from the CAH's OPO or organizations such as the Association of Organ Procurement Organizations.

Note that a patient with "severe, acute brain injury" is not always a trauma patient. For example, post myocardial infarction resuscitation may result in a patient with a beating heart and no brain activity.

The definition agreed to by the CAH and the OPO may include all of the elements listed above or just some of the elements. The definition should be tailored to fit the particular circumstances in each CAH.

CAHs may not use "batch reporting" for deaths by providing the OPO with periodic lists of patient deaths, even if instructed to do so by the OPO. If the patient dies during a transfer from one CAH to another, it is the receiving CAH's responsibility to notify the OPO.

"Timely notification" means a CAH must contact the OPO by telephone as soon as possible after an individual has died, has been placed on a ventilator due to a severe brain injury, or who has been declared brain dead (ideally within 1 hour). That is, a CAH must notify the OPO while a brain dead or severely brain-injured, ventilator-dependent individual is still attached to the ventilator and as soon as possible after the death of any other individual, including a potential non-heart-beating donor. Even if the CAH does not consider an individual who is not on a ventilator to be a potential donor, the CAH must call the OPO as soon as possible after the death of that individual has occurred.

Referral by a CAH to an OPO is timely if it is made:
o As soon as it is anticipated a patient will meet the criteria for imminent death agreed to by the OPO and CAH or as soon as possible after a patient meets the criteria for imminent death agreed to by the OPO and the CAH (ideally, within one hour); AND
o Prior to the withdrawal of any life sustaining therapies (i.e., medical or pharmacological support).

Whenever possible, referral should be made early enough to allow the OPO to assess the patient's suitability for organ donation before brain death is declared and before the option of organ donation is presented to the family of the potential donor. Timely assessment of the patient's suitability for organ donation increases the likelihood that the patient's organs will be viable for transplantation (assuming there is no disease process identified by the OPO that would cause the organs to be unsuitable), ensures that the family is approached only if the patient is medically suitable for organ donation, and ensures that an OPO representative is available to collaborate with the CAH staff in discussing donation with the family.

It is the OPO's responsibility to determine medical suitability for organ donation, and, in the absence of alternative arrangements by the CAH, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the CAH for this purpose.

Survey Procedures
o Review the CAH's written agreement with the OPO to verify that it addresses all required information.
o Verify that the CAH's governing body has approved the CAH's organ procurement policies.
o Review a sample of death records to verify that the CAH has implemented its organ procurement policies.
o Interview the staff to verify that they are aware of the CAH's policies and procedures for organ, tissue and eye procurement.
o Verify that the organ, tissue and eye donation program is integrated into the CAH's QA program.

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FED - C0346 - ORGAN, TISSUE, EYE PROCUREMENT

Title ORGAN, TISSUE, EYE PROCUREMENT

CFR 485.643(b)

Type Standard

Regulation Definition

[The CAH must have and implement written protocols that:] incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement;

Interpretive Guideline

The CAH must have an agreement with at least one tissue bank and at least one eye bank. The OPO may serve as a "gatekeeper" receiving notification about every CAH death and should notify the tissue bank chosen by the CAH about potential tissue and eye donors.

It is not necessary for a CAH to have a separate agreement with a tissue bank if it has an agreement with its OPO to provide tissue procurement services; not is it necessary for a CAH to have a separate agreement with an eye bank if its OPO provides eye procurement services. The CAH is not required to use the OPO for tissue or eye procurement but is free to have an agreement with the tissue bank or eye bank of its choice. The tissue banks and eye banks define "usable tissues" and "usable eyes".

The requirements of this regulation may be satisfied through a single agreement with an OPO that provides services for organ, tissue and eye, or by a separate agreement with another tissue and/or eye bank outside the OPO, chosen by the CAH. The CAH may continue current successful direct arrangements with tissue and eye banks as long as the direct arrangement does not interfere with organ procurement.

Survey Procedures
Verify that the CAH has an agreement with at least one tissue bank and one eye bank that specifies criteria for referral of all individuals who have died in the CAH. The agreement must also acknowledge that it is the OPO's responsibility to determine medical suitability for tissue and eye donation, unless the CAH has an alternative agreement with a different tissue and/or eye bank.

FED - C0347 - ORGAN, TISSUE, EYE PROCUREMENT

Title ORGAN, TISSUE, EYE PROCUREMENT

CFR 485.643(c)

Type Standard

Aspen Federal Regulation Set: C 04.02 CRITICAL ACCESS HOSPITALS

Regulation Definition	Interpretive Guideline
[The CAH must have and implement written protocols that:] ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its option to either donate or not donate organs, tissues, or eyes. The individual designated by the CAH to initiate the request to the family must be a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation;	It is the responsibility of the OPO to screen for medical suitability in order to select potential donors. Once the OPO has selected a potential donor, that person's family must be informed of the family's donation options. Ideally, the OPO and the CAH will decide together how and by whom the family will be approached. The individual designated by the CAH to initiate the request to the family must be a designated requestor. A "designated requestor" is defined as a CAH-designated individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community. If possible, the OPO representative and a designated requestor should approach the family together. The CAH must ensure that any "designated requestor" for organs, tissues or eyes has completed a training course either offered or approved by the OPO, which addresses methodology for approaching potential donor families. Survey Procedures o Verify that the CAH ensures that the family of each potential donor is informed of its options to donate organs, tissues, or eyes, including the option to decline to donate. o Review training schedules and personnel files to verify that all designated requestors have completed the required training. o How does the CAH ensure that only designated requestors are approaching families to ask them to donate?

FED - C0348 - ORGAN, TISSUE, EYE PROCUREMENT

Title ORGAN, TISSUE, EYE PROCUREMENT

CFR 485.643(d)

Type Standard

Regulation Definition	Interpretive Guideline
[The CAH must have and implement written protocols that:] encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors.	Using discretion does not mean a judgment can be made by the CAH that certain families should not be approached about donation. CAHs should approach the family with the belief that a donation is possible and should take steps to ensure the family is treated with respect and care. The staff's perception that a family's grief, race, ethnicity, religion or socioeconomic background would prevent donation should never be used as a reason not to approach a family.

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All potential donor families must be approached and informed of their donation rights.

Survey Procedures
o Interview a CAH-designated requestor regarding approaches to donation requests.
o Review the designated requestor training program to verify that it addresses the use of discretion.
o Review the facility complaint file for any relevant complaints.

FED - C0349 - ORGAN, TISSUE, EYE PROCUREMENT

Title ORGAN, TISSUE, EYE PROCUREMENT

CFR 485.643(e) & (f)

Type Standard

Regulation Definition

[The CAH must have and implement written protocols that ensure that:]

(e) the CAH works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes takes place.

(f) For purposes of these standards, the term "organ" means a human kidney, liver, heart, lung, pancreas, or intestines (or multivisceral organs).

Interpretive Guideline

Appropriate staff, including all patient care staff, must be trained regarding donation issues and how to work with the OPO, tissue bank and eye bank. Those CAH staff who may have to contact or work with the OPO, tissue bank and eye bank staff, must have appropriate training on donation issues including their duties and roles.

The training program must be developed in cooperation with the OPO, tissue bank and eye bank, and should include, at a minimum:
o Consent process;
o Importance of using discretion and sensitivity when approaching families;
o Role of the designated requestor;
o Transplantation and donation, including pediatrics, if appropriate;
o Quality improvement activities; and
o Role of the organ procurement organization.

Training should be conducted with new employees annually, whenever there are policy/procedure changes, or when problems are determined through the CAH's QA program.

CAHs must cooperate with OPOs, tissue banks and eye banks in regularly/periodically reviewing death records. This means that a CAH must develop policies and procedures which permit the OPO, tissue bank and eye bank access to death record information that will allow the OPO, tissue bank and eye bank to assess the CAH's donor potential, ensure that all deaths or imminent deaths are being referred to the OPO in a timely manner, and identify areas where the CAH, OPO, tissue bank and eye bank staff performance might be improved. The policies must address how patient confidentiality will be maintained during the review process.

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The CAH must have policies and procedures, developed in cooperation with the OPO, that ensure that potential donors are maintained in a manner that maintain the viability of their organs. The CAH must have policies in place to ensure that potential donors are identified and declared dead within an acceptable time frame by an appropriate practitioner.

Survey Procedures
o Review inservice training schedules and attendance sheets.
o How does the CAH ensure that all appropriate staff have attended an educational program regarding donation issues and how to work with the OPO, tissue bank, and eye bank?
o Verify by review of policies and records that the CAH works with the OPO, tissue bank, and eye bank in reviewing death records.
o Verify that the effectiveness of any protocols and policies is monitored as part of the CAH's quality improvement program.
o Validate how often the reviews are to occur. Review the protocols that are in place to guide record reviews and analysis.
o Determine how confidentiality is ensured.
o Verify that there are policies and procedures in place to ensure coordination between the facility staff and the OPO staff in maintaining the potential donor.
o Determine by review, what policies and procedures are in place to ensure that potential donors are identified and declared dead by an appropriate practitioner within an acceptable timeframe.

FED - C0350 - SPECIAL REQS FOR CAH PROVIDERS OF LTC SRVCS

Title SPECIAL REQS FOR CAH PROVIDERS OF LTC SRVCS
CFR 485.645

Type Condition

Regulation Definition

A CAH must meet the following requirements in order to be granted an approval from CMS to provide post-hospital SNF care as specified in section §409.30 of this chapter, and to be paid for SNF-level services, in accordance with paragraph (c) of this section.

Interpretive Guideline

The swing-bed concept allows a CAH to use their beds interchangeably for either acute-care or post-acute care. A "swing-bed" is a change in reimbursement status. The patient swings from receiving acute-care services and reimbursement to receiving skilled nursing (SNF) services and reimbursement.

Medicare allows a CAH to operate swing-beds through the issuance of a "swing-bed approval." If the facility fails to meet the swing-bed requirements, and the facility does not develop and implement an accepted plan of correction, the facility loses the approval to operate swing-beds and receive swing-bed reimbursement. The facility does not go on a

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termination track. If the CAH continues to meet the CoP for the provider type, it continues to operate but loses swing-bed approval.

Swing-beds need not be located in a special section of the CAH. The patient need not change locations in the facility merely because his/her status changes unless the facility requires it.

The change in status from acute care to swing-bed status can occur within one facility or the patient can be transferred from another facility for swing-bed admission.

There must be discharge orders changing status from acute care services, appropriate progress notes, discharge summary, and subsequent admission orders to swing-bed status regardless of whether the patient stays in the same facility or transfers to another facility. If the patient does not change facilities, the same chart can be utilized but the swing-bed section of the chart must be separate with appropriate admission orders, progress notes, and supporting documents.

There is no length of stay restriction for any CAH swing-bed patient. There is no Medicare requirement to place a swing-bed patient in a nursing home and there are no requirements for transfer agreements between CAHs and nursing homes.

Medicare reimbursement requires a 3-day qualifying stay in any hospital or CAH prior to admission to a swing-bed. The swing-bed stay must fall within the same spell of illness as the qualifying stay. This requirement does not apply to patients who are not receiving Medicare reimbursement.

There is no requirement for a CAH to use the MDS form for recording the patient assessment or for nursing care planning.

Swing-bed patients receive a SNF level of care, and the CAH is reimbursed for providing a SNF level of care, however swing-bed patients are not SNF patients. Swing-bed patients in CAHs are considered to be patients of the CAH.

FED - C0351 - ELIGIBILITY

Title ELIGIBILITY

CFR 485.645(a)

Type Standard

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Regulation Definition

A CAH must meet the following eligibility requirements:

(1) The facility has been certified as a CAH by CMS under §485.606(b) of this subpart; and
(2) The facility provides not more than 25 inpatient beds. Any bed of a unit of the facility that is licensed as a distinct-part SNF at the time the facility applies to the State for designation as a CAH is not counted under paragraph (a) of this section.

Interpretive Guideline

FED - C0352 - FACILITIES PARTICIPATING AS RPCH ON 9/30/1997

Title FACILITIES PARTICIPATING AS RPCH ON 9/30/1997
CFR 485.645(b)

Type Standard

Regulation Definition

These facilities [participating as rural primary care hospitals (RPCHs) on September 30, 1997] must meet the following requirements:

(1) Notwithstanding paragraph (a) of this section, a CAH that participated in Medicare as a RPCH on September 30, 1997, and on that date had in effect an approval from CMS to use its inpatient facilities to provide post-hospital SNF care may continue in that status under the same terms, conditions, and limitations that were applicable at the time these approvals were granted.

(2) A CAH that was granted swing-bed approval under paragraph (b)(1) of this section may request that its application to be a CAH and swing-bed provider be reevaluated under paragraph (a) of this section. If this request is approved, the approval is effective not earlier than October

Interpretive Guideline

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1, 1997. As of the date of approval, the CAH no longer has any status under paragraph (b)(1) of this section and may not request reinstatement under paragraph (b)(1) of this section.

FED - C0355 - PAYMENT

Title PAYMENT

CFR 485.645(c)

Type Standard

Regulation Definition	Interpretive Guideline
Payment for inpatient RPCH services to a CAH that has qualified as a CAH under the provisions in paragraph (a) of this section is made in accordance with §413.70 of this chapter. Payment for post-hospital SNF-level of care services is made in accordance with the payment provisions in §413.114 of this chapter.	

FED - C0360 - SNF SERVICES

Title SNF SERVICES

CFR 485.645(d)

Type Standard

Regulation Definition	Interpretive Guideline
The CAH is substantially in compliance with the following SNF requirements contained in subpart B of part 483 of this chapter: (1) Resident rights (§483.10(b)(3) through (b)(6), (d), (e), (h),(i), (j)(1)(vii) and (viii), (1), and (m) of this chapter). (2) Admission, transfer, and discharge rights (§483.12(a) of this chapter). (3) Resident behavior and facility practices (§483.13 of this	

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chapter).
(4) Patient activities (§483.15(f) of this chapter), except that the services may be directed either by a qualified professional meeting the requirements of §483.15(f)(2), or by an individual on the facility staff who is designated as the activities director and who serves in consultation with a therapeutic recreation specialist, occupational therapist, or other professional with experience or education in recreational therapy.
(5) Social services (§483.15(g) of this chapter).
(6)Comprehensive assessment, comprehensive care plan, and discharge planning (§483.20(b), (k), and (l) of this chapter, except that the CAH is not required to use the resident assessment instrument (RAI) specified by the State that is required under §483.20(b), or to comply with the requirements for frequency, scope, and number of assessments prescribed in §413.343(b) of this chapter).
(7) Specialized rehabilitative services (§483.45 of this chapter).
(8) Dental services (§483.55 of this chapter).
(9) Nutrition (§483.25(i) of this chapter).

FED - C0361 - RESIDENTS RIGHTS (483.10(b)(3))

Title RESIDENTS RIGHTS (483.10(b)(3))

CFR 485.645(d)(1)

Type Standard

Regulation Definition

The resident has a right to a dignified existence, self-determination, and communication with and access to persons and services inside and outside the facility. A facility must protect and promote the rights of each resident, including the right to be fully informed in language that he or she can understand of his or her total health status, including but not limited to, his or her medical condition.

Interpretive Guideline

The intent of this requirement is to assure that each resident knows his or her rights and responsibilities and that the facility communicates this information prior to or upon admission, during the resident's stay, and when the facility's rules changes. A facility must promote the exercise of rights for all residents, including those who face barriers such as communication problems, hearing problems and cognition limits. These rights include the resident's right to:
o Be informed about what rights and responsibilities the resident has (§483.10(b)(3 through 6));
o Choose a personal attending physician (§483.10(d));
o Participate in decisions about treatment and care planning (§483.10(d));
o Have privacy and confidentiality (§483.10(e));

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o Work or not work (§483.10(h));
o Have privacy in sending and receiving mail (§483.10(i));
o Visit and be visited by others from outside the facility (§483.10(j)(1)(vii and viii));
o Retain and use personal possessions (§483.10(l)); and
o Share a room with a spouse (§483.10(m)).

"Total health status" includes functional status, medical care, nursing care, nutritional status, rehabilitation and restorative potential, activities potential, cognitive status, oral health status, psychosocial status, and sensory and physical impairments. Information on health status must be presented in language that the resident can understand.

Communicating with the resident in language that the resident can understand includes minimizing the use of technical words, providing interpreters for non-English speaking residents, using sign language when needed, or other interventions, as appropriate.

Survey Procedures
o Look for on-going efforts on the part of facility staff to keep residents informed.
o Look for evidence that information is communicated in a manner that is understandable to residents.
o Is information available when it is most useful to the residents such as when they are expressing concerns, raising questions, and on an on-going basis?
o Is there evidence in the medical record that the patient was informed of his rights, including the right to accept or refuse medical or surgical treatment?

FED - C0362 - RESIDENTS RIGHTS (483.10(b)(4))

Title RESIDENTS RIGHTS (483.10(b)(4))

CFR 485.645(d)(1)

Type Standard

Regulation Definition

The resident has the right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive as specified in paragraph (8) of this section.

Interpretive Guideline

"Treatment" is defined as care provided for purposes of maintaining/restoring health, improving functional level, or relieving symptoms.

"Experimental research" is defined as development and testing of clinical treatments, such as an investigational drug or therapy that involve treatment and/or control groups. For example, a clinical trial of an investigational drug would be experimental research.

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"Advance directive" means a written instruction, such as living will or durable power of attorney for health care, recognized under state law, relating to the provisions of health care when the individual is incapacitated.

A resident who has the capacity to make a health care decision and who withholds consent to treatment or makes an explicit refusal of treatment either directly or through an advance directive, may not be treated against his/her wishes.

The resident has the right to refuse to participate in experimental research. A resident being considered for participation in experimental research must be fully informed of the nature of the experiment and understand the possible consequences of participating. The opportunity to refuse to participate in experimental research must occur prior to the start of the research. Aggregated resident statistics that do not identify individual residents may be used for studies without obtaining resident permission.

Survey Procedures §483.10(b)(4)
If the facility participates in any experimental research involving residents, does it have an Institutional Review Board or other committee that reviews and approves research protocols? The requirement at §483.75(c) Relationship to Other HHC Regulations may apply, (see 45 CFR Part 46, Protection of Human Subjects of Research). "Although these regulations at §483.75(c) are not in themselves considered requirements under this part, their violation may result in the termination or suspension of, or the refusal to grant or continue payment with Federal funds."

NOTE: 42 CFR §483.10(b)(8), containing advance directive requirements, guidelines, procedures and probes, is contained below.
o §483.10(b)(8) The facility must comply with the requirements specified in subpart I of part 489 of this chapter relating to maintaining written policies and procedures regarding advance directives. These requirements include provisions to inform and provide written information to all adult residents concerning the right to accept or refuse medical or surgical treatment and, at the individual's option, formulate an advance directive. This includes a written description of the facility's policies to implement advance directives and applicable State law. Facilities are permitted to contract with other entities to furnish this information but are still legally responsible for ensuring that the requirements of this section are met. If an adult individual is incapacitated at the time of admission and is unable to receive information (due to the incapacitating condition or a mental disorder) or articulate whether or not he or she has executed an advance directive, facility may give advance directive information to the individual's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated individual or to a surrogate or other concerned persons in accordance with State law. The facility is not relieved of its obligation to provide this information to the individual once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to provide the information to the individual directly at the appropriate time.

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"Advance directive" means a written instruction, such as a living will or durable power of attorney for health care recognized under State law, relating to the provision of health care when the individual is incapacitated.

Interpretive Guidelines §483.10(b)(8)
This provision applies to residents admitted on or after December 1, 1991. The regulation at 42 CFR §489.102 specifies that at the time of admission of an adult resident, the facility must:
o Maintain written policies and procedures concerning advance directives with respect to all adult individuals receiving medical care;
o Provide written information concerning his or her rights under State law (whether statutory or recognized by the courts of the State) to make decisions concerning medical care, including the right to accept or refuse medical or surgical treatment, and the right to formulate advance directives;
o Document in the resident's medical record whether or not the individual has executed an advance directive;
o Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive;
o Ensure compliance with requirements of State law regarding advance directives;
o Provide for educating staff regarding the facility's policies and procedures on advance directives; and
o Provide for community education regarding issues concerning advance directives.

The facility is not required to provide care that conflicts with an advance directive. In addition, the facility is also not required to implement an advance directive if, as a matter of conscience, the provider cannot implement an advance directive, and state law allows the provider to conscientiously object.

The sum total of the community education efforts must include a summary of the state law, the rights of residents to formulate advance directives, and the facility's implementation policies regarding advance directives. Video and audiotapes may be used in conducting the community education effort. Individual education programs do not have to address all the requirements if it would be inappropriate for a particular audience.

Survey Procedures §483.10(b)(8)
o Review the records of sampled residents admitted on or after December 1, 1991, for facility compliance with advance directive notice requirements.
o Determine to what extent the facility educates its staff regarding advance directives.
o Determine to what extent the facility provides education for the community regarding individual rights under State law to formulate advance directives.

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FED - C0363 - RESIDENTS RIGHTS (483.10(b)(5))

Title RESIDENTS RIGHTS (483.10(b)(5))

CFR 485.685(d)(1)

Type Standard

Regulation Definition

The facility must Inform each resident who is entitled to Medicaid benefits, in writing, at the time of admission to the nursing facility or, when the resident becomes eligible for Medicaid of the items and services that are included in nursing facility services under the State plan and for which the resident may not be charged; those other items and services that the facility offers and for which the resident may be charged, and the amount of charges for those services; and inform each resident when changes are made to the items and services specified in paragraphs (5)(i)(A) and (B) of this section.

The facility must inform each resident before, or at the time of admission, and periodically during the resident's stay, of services available in the facility and of charges for those services, including any charges for services not covered under Medicare or by the facility's per diem rate.

Interpretive Guideline

If Medicare or Medicaid does not make payment for services, the provider must fully inform the resident of any related charges both at the time of admission and prior to the time that changes will occur in their bills.

Listed below are general categories and examples of items and services that the facility may charge to resident funds, if they are requested and agreed to by a resident.
o Telephone;
o Television/radio for personal use;
o Personal comfort items including smoking materials, notions, novelties, and confection;
o Cosmetic and grooming items and services in excess of those for which payment is made;
o Personal clothing;
o Personal reading matter;
o Gifts purchased on behalf of a resident;
o Flowers and plants;
o Social events and entertainment offered outside the scope of the activities program;
o Non-covered special care services such as privately hired nurses or aides;
o Private room, except when therapeutically required, for example, isolation for infection control;
o Specially prepared or alternative food requested.

FED - C0364 - FREE CHOICE (483.10(d)(1))

Title FREE CHOICE (483.10(d)(1))

CFR 485.645(d)(1)

Type Standard

Regulation Definition

The resident has the right to choose a personal attending

Interpretive Guideline

The right to choose a personal physician does not mean that the physician must serve the resident. If the physician of

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physician.

the resident's choosing fails to fulfill a given requirement, such as frequency of physician visits, the facility will have the right, after informing the resident, to seek alternate physician participation to assure provision of appropriate and adequate care and treatment. A facility may not place barriers in the way of residents choosing their own physician. If a resident does not have a physician, or if the resident's physician becomes unable or unwilling to continue providing care to the resident, the facility must assist the resident in exercising his/her choice in finding another physician. A resident can choose his/her own physician, but cannot have a physician who does not have swing bed admitting privileges.

The requirement for free choice is met if a resident is allowed to choose a personal physician from among those who have practice privileges.

FED - C0365 - FREE CHOICE (483.10(d)(2))

Title FREE CHOICE (483.10(d)(2))

CFR 485.645(d)(1)

Type Standard

Regulation Definition

The resident has the right to be fully informed in advance about care and treatment and of any changes in that care or treatment that may affect the resident's well-being.

Interpretive Guideline

"Informed in advance" means that the resident receives information necessary to make a health care decision. The information should include his/her medical condition, changes in his/her medical condition, the benefits and reasonable risks of the recommended treatment, and reasonable alternatives. If there are any financial costs to the resident in the treatment options, they should be disclosed in advance and in writing to the resident prior to his/her decision.

FED - C0366 - FREE CHOICE (483.10(d)(3))

Title FREE CHOICE (483.10(d)(3))

CFR 485.645(d)(1)

Type Standard

Regulation Definition

The resident has a right, unless adjudged incompetent or otherwise found to be incapacitated under the laws of the State, to participate in planning care and treatment or changes

Interpretive Guideline

"Participates in planning care and treatment" means that the resident is afforded the opportunity to select from alternative treatments, to the level of his ability to understand. This applies both to initial decisions about care and treatment and to decisions about changes in care and treatment. The resident has the right to participate in care

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in care and treatment.

planning and to refuse treatment.

Survey Procedures
o Look for evidence that the resident was afforded the right to participate in care planning or was consulted about care and treatment changes.
o If there appears to be a conflict between a resident's right and the resident's health or safety, determine if the facility attempted to accommodate both the exercise of the resident's rights and the resident's health, including exploration of care alternatives through a thorough care planning process in which the resident may participate.
o If a resident whose ability to make decisions about care and treatment is impaired, was he kept informed and consulted on personal preferences to the level of his ability to understand?

FED - C0367 - PRIVACY & CONFIDENTIALITY (483.10(e))

Title PRIVACY & CONFIDENTIALITY (483.10(e))

CFR 485.645(d)(1)

Type Standard

Regulation Definition

The resident has the right to personal privacy and confidentiality for his or her personal and clinical records. Personal privacy includes accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups, but this does not require the facility to provide a private room for a resident.

Except as provided in paragraph (e)(3) of this section, the resident may approve or refuse the release of personal and clinical records to any individual outside the facility.

The resident's right to refuse release of personal and clinical records does not apply when the resident is transferred to another health care institution or record release is required by law.

Interpretive Guideline

"Right to personal privacy" means that the resident has the right to privacy with whomever the resident wishes to be private and that this privacy should include both visual and auditory privacy. Private space may be created flexibly and need not be dedicated solely for visitation purposes.

For example, privacy for visitation or meetings might be arranged by using a dining area between meals, a vacant chapel, office or room; or an activities area when activities are not in progress. Arrangements for private space could be accomplished through cooperation between the facility's administration and resident or family groups so that private space is provided for those requesting it without infringement on the rights of other residents.

Facility staff must examine and treat residents in a manner that maintains the privacy of their bodies. A resident must be granted privacy when going to the bathroom and in other activities of personal hygiene. If an individual requires assistance, authorized staff should respect the individual's need for privacy. Only authorized staff directly involved in treatment should be present when treatments are given. People not involved in the care of the individual should not be present without the individual's consent while he/she is being examined or treated. Staff should pull privacy curtains, close doors, or otherwise remove residents from public view and provide clothing or draping to prevent unnecessary exposure of body parts during the provision of personal care and services.

Survey Procedures

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o Document any instances where you observe a resident's privacy being violated. Completely document how the resident's privacy was violated.
o Documentation Example: Resident #12 left without gown or bed covers and unattended on 2B Corridor at 3:30 p.m. February 25, 2001. Identify the responsible party, if possible.

FED - C0368 - WORK (483.10(h))

Title WORK (483.10(h))

CFR 485.645(d)(1)

Type Standard

Regulation Definition

The resident has the right to refuse to perform services for the facility or perform services for the facility, if he or she chooses, when the facility has documented the need or desire for work in the plan of care; the plan specifies the nature of the services performed and whether the services are voluntary or paid; compensation for paid services is at or above prevailing rates; and the resident agrees to the work arrangement described in the plan of care.

Interpretive Guideline

All resident work, whether of a voluntary or paid nature, must be part of the plan of care. A resident's desire for work is subject to medical appropriateness. As part of the plan of care, a therapeutic work assignment must be agreed to by the resident. The resident also has the right to refuse such treatment at any time that he or she wishes. At the time of development or review of the plan, voluntary or paid work can be negotiated.

The "prevailing rate" is the wage paid to workers in the community surrounding the facility for the same type, quality, and quantity of work requiring comparable skills.

Survey Procedures
o Are residents engaged in work (e.g., doing housekeeping, doing laundry, preparing meals)?
o Pay special attention to the possible work activities of residents with mental retardation or mental illness.
o If a resident is performing work, determine whether it is voluntary, and whether it is described in the plan of care. Is the work mutually agreed upon between the resident and the treatment team?

FED - C0369 - MAIL (483.10(i))

Title MAIL (483.10(i))

CFR 485.645(d)(1)

Type Standard

Regulation Definition

The resident has the right to privacy in written

Interpretive Guideline

"Promptly" means delivery of mail or other materials to the resident within 24 hours of delivery by the postal service

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communications, including the right to send and promptly receive mail that is unopened, and have access to stationery, postage, and writing implements at the resident's own expense.

(including a post office box) and delivery of outgoing mail to the postal service within 24 hours of regularly scheduled postal delivery and pickup service.

FED - C0370 - ACCESS AND VISITATION RIGHTS (483.10(j))

Title ACCESS AND VISITATION RIGHTS (483.10(j))

CFR 485.645(d)(1)

Type Standard

Regulation Definition

The resident has the right and the facility must provide immediate access to any resident by any representative of the Secretary; subject to the resident's right to deny or withdraw consent at any time, immediate family or other relatives of the resident; and, subject to reasonable restrictions and the resident's right to deny or withdraw consent at any time, others who are visiting with the consent of the resident.

Interpretive Guideline

The facility may set reasonable hours for visitation.

If it would violate the rights of a roommate to have visitors in the resident's room, the facility must establish alternate areas in the facility for visiting. These areas could include the chapel, a suitable office area, a dining room, or a porch or patio area.

FED - C0371 - PERSONAL PROPERTY (483.10(l))

Title PERSONAL PROPERTY (483.10(l))

CFR 485.645(d)(1)

Type Standard

Regulation Definition

The resident has the right to retain and use personal possessions, including some furnishings, and appropriate clothing, as space permits, unless to do so would infringe upon the rights and safety of other residents.

Interpretive Guideline

The intent of this regulation is to encourage residents to bring personal possessions into the facility, as space, safety considerations and fire code permits. All residents' possessions must be treated with respect and safeguarded.

The facility has the right to limit personal property due to space limitations in the facility or for safety considerations.

Survey Procedures
If residents' rooms have few personal possessions, ask residents and families if--
o They are encouraged to have and to use personal items;

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o Their personal property is safe in the facility.

FED - C0372 - MARRIED COUPLES (483.10(m))

Title MARRIED COUPLES (483.10(m))

CFR 485.645(d)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The resident has the right to share a room with his or her spouse when married residents live in the same facility and both spouses consent to the arrangement.	The requirement means that when a room is available for a married couple to share, the facility must permit them to share it if they choose.

FED - C0373 - ADMISSION, TRANSFER, DISCHARGE(483.12(a)(1))

Title ADMISSION, TRANSFER, DISCHARGE(483.12(a)(1))

CFR 485.645(d)(2)

Type Standard

Regulation Definition	Interpretive Guideline
Transfer and discharge includes movement of a resident to a bed outside of the certified facility whether that bed is in the same physical plant or not. Transfer and discharge does not refer to movement of a resident to a bed within the same certified facility.	The intent of the regulation on transfer and discharge provisions is to significantly restrict a facility's ability to transfer or discharge a resident once that resident has been admitted to the facility to prevent dumping of high care or difficult residents. This requirement applies to transfer or discharges that are initiated by the facility, not by the resident.

FED - C0374 - TRANSFER AND DISCHARGE (483.12(a)(2))

Title TRANSFER AND DISCHARGE (483.12(a)(2))

CFR 485.645(d)(2)

Type Standard

Aspen Federal Regulation Set: C 04.02 CRITICAL ACCESS HOSPITALS

Regulation Definition

The facility must permit each resident to remain in the facility, and not transfer or discharge the resident from the facility unless the transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the facility; or the transfer or discharge is appropriate because the resident's health has improved sufficiently so the resident no longer needs the services provided by the facility; or the safety of individuals in the facility is endangered; or the health of individuals in the facility would otherwise be endangered; or the resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility.

For a resident who becomes eligible for Medicaid after admission to a facility, the facility may charge a resident only allowable charges under Medicaid; or the facility ceases to operate.

Interpretive Guideline

If transfer is due to a significant change in the resident's condition, the facility must conduct the appropriate assessment, prior to any transfer or discharge to determine if a new care plan would allow the facility to meet the resident's needs.

If the significant change in the resident's condition is an emergency, immediate transfer should be arranged.

Survey Procedures
During closed record review, determine the reasons for transfer/discharge.
o Do records document accurate assessments and attempts through care planning to address the resident's needs through multidisciplinary interventions, accommodation of individual needs, and attention to the resident's customary routine?
o Did the resident's physician document the record if the resident was transferred/discharged for the sake of the resident's welfare and the resident's needs could not be met in the facility (e.g., a resident develops an acute condition requiring hospitalization) or the resident's health improved to the extent that the transferred/discharged resident no longer needed the services of the facility?
o Did a physician document the record if residents were transferred because the health of individuals in the facility is endangered?
o Do the records of residents who are transferred/discharged due to safety reasons reflect the process by which the facility concluded that in each instance transfer or discharge was necessary?
o If the entity to which the resident was discharged is another long term care facility, evaluate the extent to which the discharge summary and the resident's physician justify why the facility could not meet the needs of this resident.

FED - C0376 - DOCUMENTATION (483.12(a)(3))

Title DOCUMENTATION (483.12(a)(3))

CFR 485.645(d)(2)

Type Standard

Regulation Definition

When the facility transfers or discharges a resident under any of the circumstances specified in paragraphs (a)(2)(i) through (v) of this section, the resident's clinical record must be documented. The documentation must be made by the

Interpretive Guideline

Documentation of the transfer/discharge may be completed by a physician extender unless prohibited by State law or facility policy.

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resident's physician when transfer or discharge is necessary under paragraph (a)(2)(i) or paragraph (a)(2)(ii) of this section; and a physician when transfer or discharge is necessary under paragraph (a)(2)(iv) of this section.

FED - C0377 - NOTICE BEFORE TRANSFER (483.12(a)(4))

Title NOTICE BEFORE TRANSFER (483.12(a)(4))

CFR 485.645(d)(2)

Type Standard

Regulation Definition

Before a facility transfers or discharges a resident, the facility must notify the resident and, if known, a family member or legal representative of the resident of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand; record the reasons in the resident's clinical record; and include in the notice the items described in paragraph (a)(6) of this section.

Interpretive Guideline

FED - C0378 - TIMING OF THE NOTICE (483.12(a)(5))

Title TIMING OF THE NOTICE (483.12(a)(5))

CFR 485.645(d)(2)

Type Standard

Regulation Definition

Except when specified in paragraph (a)(5)(ii) of this section, the notice of transfer or discharge required under paragraph (a)(4) of this section must be made by the facility at least 30 days before the resident is transferred or discharged.

Notice may be made as soon as practicable before transfer or discharge when the safety of individuals in the facility would

Interpretive Guideline

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be endangered under paragraph (a)(2)(iii) of this section; or the health of individuals in the facility would be endangered, under paragraph (a)(2)(iv) of this section; or the resident's health improves sufficiently to allow a more immediate transfer or discharge, under paragraph (a)(2)(ii) of this section; or an immediate transfer or discharge is required by the resident's urgent medical needs, under paragraph (a) (2)(i) of this section; or a resident has not resided in the facility for 30 days.

FED - C0379 - CONTENTS OF NOTICE (473.12(a)(6))

Title CONTENTS OF NOTICE (473.12(a)(6))

CFR 485.645(d)(2)

Type Standard

Regulation Definition

The written notice specified in paragraph (a)(4) of this section must include the following.
o The reason for transfer or discharge;
o The effective date of transfer or discharge;
o The location to which the resident is transferred or discharged;
o A statement that the resident has the right to appeal the action to the State; and
o The name, address and telephone number of the State long term care ombudsman.
o For nursing facility residents with developmental disabilities, the mailing address and telephone number of the agency responsible for the protection and advocacy of developmentally disabled individuals established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act.
o For nursing facility residents who are mentally ill, the mailing address and telephone number of the agency responsible for the protection and advocacy for mentally ill

Interpretive Guideline

individuals established under the Protection and Advocacy for Mentally Ill Individuals Act.

FED - C0380 - ORIENTATION FOR DISCHARGE (483.12(a)(7))

Title ORIENTATION FOR DISCHARGE (483.12(a)(7))

CFR 485.645(d)(2)

Type Standard

Regulation Definition	Interpretive Guideline
A facility must provide sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility.	"Sufficient preparation" means the facility informs the resident where he or she is going and assures safe transportation. The facility should actively involve the resident and the resident's family in selecting the new residence. Some examples of orientation may include trial visits by the resident to a new location; working with family; and orienting staff in the receiving facility to the resident's daily patterns. Survey Procedures During resident reviews, check social service notes to see if appropriate referrals have been made and, if necessary, if resident counseling has occurred.

FED - C0381 - RESTRAINTS (483.13(a))

Title RESTRAINTS (483.13(a))

CFR 485.645(d)(3)

Type Standard

Regulation Definition	Interpretive Guideline
The resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms.	The intent of this requirement is for each person to reach his/her highest practicable well-being in an environment that prohibits the use of restraints for discipline or convenience and limits restraint use to circumstances in which the resident has medical symptoms that warrant the use of restraints. "Physical restraints" are defined as any manual method or physical or mechanical device, material, or equipment attached or adjacent to the resident's body that the individual cannot remove easily and that restricts freedom of movement or normal access to one's body.

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"Chemical Restraint" is defined as a psychopharmacologic drug that is used for discipline or convenience and not required to treat medical symptoms.

"Discipline" is defined as any action taken by the facility for the purpose of punishing or penalizing residents.

"Convenience" is defined as any action taken by the facility to control resident behavior or maintain residents with a lesser amount of effort by the facility and not in the resident's best interest.

Medical symptoms that would warrant the use of restraints should be reflected in the comprehensive assessment and care planning. The facility must engage in a systematic and gradual process toward reducing restraints (e.g., gradually increasing the time for ambulation and muscle strengthening activities).

Survey Procedures
o Determine if the facility follows a systematic process of evaluation and care planning prior to using restraints.
o Determine if the interdisciplinary team addressed the risk of decline at the time restraint use was initiated.
o Did the team institute measures in the care plan to address reversal of any decline in health status?
o Determine the intended use of any restraints. Was the use for convenience or discipline?

FED - C0382 - ABUSE (483.13(b))

Title ABUSE (483.13(b))

CFR 485.645(d)(3)

Type Standard

Regulation Definition

The resident has the right to be free from verbal, sexual, physical, and mental abuse, corporal punishment, and involuntary seclusion.

Interpretive Guideline

The intent of this regulation is to assure that each resident is free from abuse, corporal punishment, and involuntary seclusion. The facility is responsible for preventing abuse, but also for those practices and omissions, neglect and misappropriation of property, which if left unchecked, lead to abuse.

Residents must not be subjected to abuse by anyone, including, but not limited to, facility staff, other residents, consultants or volunteers, staff of other agencies serving the individual, family members or legal guardians, friends, or other individuals.

"Abuse" is defined as the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm or pain or mental anguish, or deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well being. This presumes that

instances of abuse of all residents, even those in a coma, cause physical harm, or pain or mental anguish.

"Verbal abuse" is defined as any use of oral, written or gestured language that willfully includes disparaging and derogatory terms to residents or their families, or within their hearing distance, regardless of their age, ability to comprehend, or disability. Examples of verbal abuse include, but are not limited to: threats of harm; and saying things to frighten a resident, such as telling a resident that she will never be able to see her family again.

"Sexual abuse" includes, but is not limited to, sexual harassment, sexual coercion, or sexual assault.

"Physical abuse" includes hitting, slapping, pinching and kicking. It also includes controlling behavior through corporal punishment and restraints.

"Mental abuse" includes, but is not limited to, humiliation, harassment, and threats of punishment or deprivation.

"Involuntary seclusion" is defined as separation of a resident from other residents or from his or her room or confinement to his or her room (with or without roommates) against the resident's will, or the will of the resident's legal representative. Emergency or short term monitored separation from other residents will not be considered involuntary seclusion and may be permitted if used for a limited period of time as a therapeutic intervention to reduce agitation until professional staff can develop a plan of care to meet the resident's needs.

Survey Procedures
o Offsite, pre-survey review of complaints can focus the survey team's on-site review of actual incidents and predisposing factors to abuse or neglect and misappropriation of property.
o Report and record any instances where the survey team observes an abusive incident. Completely document who committed the abusive act, the nature of the abuse, and where and when it occurred. Ensure that the facility addresses that incident immediately.
o If the survey team's observations and resident's responses signal the presence of abuse, determine how the facility prevents and reports abusive behavior.
o If a resident is being temporarily separated from other residents, for less than 24 hours, as an emergency short-term intervention, answer these questions--
- What are the symptoms that led to the consideration of the separation?
- Are these symptoms caused by failure to--
  o Meet individual needs;
  o Provide meaningful activities;
  o Manipulate the resident's environment?

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- Can the cause(s) be removed?
- If the cause(s) cannot be removed, has the facility attempted to use alternatives short of separation?
- Does the facility use the separation for the least amount of time?
- To what extent has the resident, surrogate or representative participated in care planning and made an informed choice about separation?
- Does the facility monitor and adjust care to reduce negative outcomes, while continually trying to find and use less restrictive alternatives?
- If residents are temporarily separated in secured units, staff should carry keys to these units at all times.
- If the purpose of the unit is to provide specialized care for residents who are cognitively impaired (through a program of therapeutic activities designed to enable residents to attain and maintain the highest practicable physical, mental or psychosocial well-being) then placement in the unit is not in violation of resident rights, as long as the resident's individual care plan indicates the need for the stated purpose and services provided in the unit and the resident, surrogate, or representative has participated in the placement decision.

FED - C0383 - STAFF TREATMENT OF RESIDENTS (483.13(c))

Title STAFF TREATMENT OF RESIDENTS (483.13(c))

CFR 485.645(d)(3)

Type Standard

Regulation Definition

The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property. The facility must not use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion.

Interpretive Guideline

The intent of this regulation is to assure that the facility has in place an effective system that prevents mistreatment, neglect and abuse of residents, and misappropriation of resident's property.

"Misappropriation of resident's property" is defined as the patterned or deliberate misplacement, exploitation, or wrongful, temporary or permanent use of a resident's belongings or money without the resident's consent.

FED - C0384 - STAFF TREATMENT OF RESIDENTS (483.13(c))

Title STAFF TREATMENT OF RESIDENTS (483.13(c))

CFR 485.645(d)(3)

Type Standard

Aspen Federal Regulation Set: C 04.02 CRITICAL ACCESS HOSPITALS

Regulation Definition

The facility must not employ individuals who have been found guilty of abusing, neglecting, or mistreating residents by a court of law; have had a finding entered into the State nurse aide registry concerning abuse, neglect, mistreatment of residents or misappropriation of their property; and report any knowledge it has of actions by a court of law against an employee, which would indicate unfitness for service as a nurse aide or other facility staff to the State nurse aide registry or licensing authorities.

The facility must ensure that all alleged violations involving mistreatment, neglect, or abuse, including injuries of unknown source and misappropriation of resident property are reported immediately to the administrator of the facility and to other officials in accordance with State law through established procedures (including to the State survey and certification agency).

The facility must have evidence that all alleged violations are thoroughly investigated, and must prevent further potential abuse while the investigation is in progress.

The results of all investigations must be reported to the administrator or his designated representative and to other officials in accordance with State law (including to the State survey and certification agency) within 5 working days of the incident and if the alleged violation is verified, appropriate corrective action must be taken.

Interpretive Guideline

The intent of this regulation is to prevent employment of individuals who have been convicted of abusing, neglecting, or mistreating individuals in a health care related setting.

In addition to inquiry of the State nurse aide registry or other licensing authorities, the facility should check all staff references and make reasonable efforts to uncover information about any past criminal prosecutions.

"Found guilty...by a court of law" applies to situations where the defendant pleads guilty, is found guilty, or pleads nolo contendere.

"Finding" is defined as a determination made by the State that validates allegations of abuse, neglect, mistreatment of residents or misappropriation of their property.

Any facility staff found guilty of neglect, abuse, or mistreating residents or misappropriation of property by a court of law, must have his or her name entered into the nurse aide registry, or reported to the licensing authority, as appropriate.

Survey Procedures
During Sample Selection--
o If the team has identified a problem in mistreatment, neglect or abuse of residents or misappropriation of their property, then request--
- A copy of the facility's policies and procedures regarding abuse prevention: Note particularly the extent to which those policies concern the areas uncovered through complaints and/or previous survey;
- Reports of action(s) by a court of law against employees;
- Reports of alleged violations involving mistreatment, neglect, abuse, injuries of unknown source, and misappropriation of resident's property;
- Reports of the results of these investigations; and
- Records of corrective actions taken.
o Spot check employment applications for questions about convictions or mistreatment, neglect or abuse of residents, or misappropriation of their property. Determine if applicants have answered these questions and if affirmative answers had resulted in rejections of employment candidates.
o Contact the State Nurse Aide Registry or Board of Nursing, as appropriate. Determine if applicants with a finding concerning mistreatment, neglect, and abuse of residents or misappropriation of their property have been rejected.
o Ask for the results of any in-house investigations of mistreatment, neglect, or abuse of residents, misappropriation of their property, or injuries of unknown sources.
- Was the administrator notified of the incident and when?

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- Did investigations begin promptly after the report of the problem?
- Is there a record of statements or interviews of the resident, suspect (if one is identified), any eyewitnesses and any circumstantial witnesses?
- Was relevant documentation reviewed and preserved (e.g., dated dressing which was not changed when treatment recorded change)?
- Was the alleged victim examined promptly (if injury was suspected) and the finding documented in the report?
- What steps were taken to protect the alleged victim from further abuse (particularly where no suspect has been identified)?
- What actions were taken as a result of the investigation?
- What corrective action was taken, including informing the nurse aide registry, State licensure authorities, and other agencies (e.g., long-term care ombudsman; adult protective services; Medicaid fraud and abuse unit)?

FED - C0385 - PATIENT ACTIVITIES (483.15(f))

Title PATIENT ACTIVITIES (483.15(f))

CFR 485.645(d)(4)

Type Standard

Regulation Definition

A facility must care for its residents in a manner and in an environment that promotes maintenance or enhancement of each resident's quality of life. The facility must provide for an ongoing program of activities designed to meet, in accordance with the comprehensive assessment, the interests and the physical, mental, and psychosocial well-being of each resident.

The activities program must be directed by a qualified professional who is a qualified therapeutic recreation specialist or an activities professional who--
o Is licensed or registered, if applicable, by the State in which practicing; and
o Is eligible for certification as a therapeutic recreation specialist or as an activities professional by a recognized accrediting body on or after October 1, 1990; or
o Has 2 years of experience in a social or recreational program

Interpretive Guideline

A "recognized accrediting body" refers to those organizations or associations recognized as such by certified therapeutic recreation specialists or certified activity professionals or registered occupational therapists.

The activities program should be multi-faceted and reflect individual residents' needs on their care plan. Activities can occur at anytime and are not limited to formal activities being provided by activity staff. Others involved may be any facility staff, volunteers, and visitors.

In a Critical Access Hospital, the services at §483.15(f) may be directed either by a qualified professional meeting the requirements of §483.15(f)(2), or by an individual on the facility staff who is designated as the activities director and who serves in consultation with a therapeutic recreation specialist, occupational therapist, or other professional with experience or education in recreational therapy.

Survey Procedures
o Observe individual, group and bedside activities.
- Are residents who are confined or choose to remain in their rooms provided with suitable in-room activities (e.g., music, reading, visits with individuals who share their interests)? Do any facility staff members assist the resident with activities?

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within the last 5 years, 1 of which was full-time in a patient activities program in a health care setting; or
o Is a qualified occupational therapist or occupational therapy assistant; or
o Has completed a training course approved by the State.

o If residents sit for long periods of time with no apparently meaningful activities, is the cause--
- The resident's choice;
- Failure of any staff or volunteers either to inform residents when activities are occurring or to encourage resident involvement in activities;
- Lack of assistance with ambulation;
- Lack of sufficient supplies and/or staff to facilitate attendance and participation in the activity programs; or
- Program design that fails to reflect the interests or ability levels of residents, such as activities that are too complex?

o For residents selected for review, or a focused review, determine to what extent the activities reflect the individual resident's assessment.
o Review the activity calendar for the month prior to the survey to determine if the formal activity program:
- Reflects the schedules, choices and rights of the residents;
- Offers activities at hours convenient to the residents (e.g., morning, afternoon, some evenings and weekends);
- Reflects the cultural and religious interests of the resident population; and
- Would appeal to both men and women and all age groups living in the facility.

o Review clinical records and activity attendance records of residents to determine if--
- Activities reflect individual resident history indicated by the comprehensive assessment;
- Care plans address activities that are appropriate for each resident based on the comprehensive assessment;
- Activities occur as planned; and
- Outcomes/responses to activities interventions are identified in the progress notes of each resident.

o If there are problems with provision of activities, determine if qualified staff provide these service.

FED - C0386 - SOCIAL SERVICES (483.15(g))

Title SOCIAL SERVICES (483.15(g))

CFR 485.645(d)(5)

Type Standard

Regulation Definition

The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

A facility with more than 120 beds must employ a qualified social worker on a full-time basis.

Interpretive Guideline

The intent of this regulation is to assure that all facilities provide for the medically-related social services needs of each resident. This requirement specifies that facilities aggressively identify the need for medically-related social services, and pursue the provision of these services. A qualified social worker need not personally provide all of these services. It is the responsibility of the facility to identify the medically-related social service needs of the resident and assure that the needs are met by the appropriate discipline.

"Medically-related social services" means services provided by the facility's staff to assist residents in maintaining or

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A qualified social worker is an individual with a bachelor's degree in social work or a bachelor's degree in a human services field including but not limited to sociology, special education, rehabilitation counseling, and psychology; and one year of supervised social work experience in a health care setting working directly with individuals.

improving their ability to manage their everyday physical, mental, and psychosocial needs. These services could include:
o Assisting residents with financial and legal matters (e.g., applying for pensions, referrals to lawyers, referrals to funeral homes for preplanning arrangements);
o Discharge planning services (e.g., helping to place a resident on a waiting list for community congregate living, arranging intake for home care services for residents returning home, assisting with transfer arrangements to other facilities);
o Providing or arranging provision of needed counseling services;
o Assisting residents to determine how they would like to make decisions about their health care, and whether or not they would like anyone else to be involved in those decisions;
o Finding options that meet the physical and emotional needs of each resident;
o Meeting the needs of residents who are grieving; and
o Assisting residents with dental/denture care, podiatric care; eye care; hearing services, and obtaining equipment for mobility or assistive eating devices.

Where the Medicaid State Plan does not cover needed services, facilities are still required to attempt to obtain these services.

Survey Procedures
For residents selected for review--
o How do facility staff implement social services interventions to assist the resident in meeting treatment goals?
o How do staff that are responsible for social work monitor the resident's progress in improving physical, mental and psychosocial functioning? Has goal attainment been evaluated and the care plan changed accordingly?
o How does the care plan link goals to psychosocial functioning/well being?
o Has the staff responsible for social work established and maintained relationships with the resident's family or legal representative?
o What attempts does the facility make to access services for Medicaid recipients when a Medicaid State Plan does not cover those services?
o Look for evidence that social services interventions successfully address residents' needs and link social supports, physical care, and physical environment with residents' needs and individuality.

FED - C0388 - RESIDENT ASSESSMENT (483.20(b)(1))

Title RESIDENT ASSESSMENT (483.20(b)(1))

CFR 485.645(d)(6)

Type Standard

Aspen Federal Regulation Set: C 04.02 CRITICAL ACCESS HOSPITALS

Regulation Definition

The facility must conduct initially and periodically a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity.

A facility must make a comprehensive assessment of a resident's needs. The assessment must include at least the following:
Identification and demographic information;
Customary routine;
Cognitive patterns;
Communication;
Vision;
Mood and behavior patterns;
Psychosocial well-being;
Physical functioning and structural problems;
Continence;
Disease diagnoses and health conditions;
Dental and nutritional status;
Skin condition;
Activity pursuit;
Medications;
Special treatments and procedures;
Discharge potential;
Documentation of summary information regarding the additional assessment performed through the resident assessment protocols; and
Documentation of participation in assessment.

The assessment process must include direct observation and communication with the resident, as well as communication with licensed and non-licensed direct care staff members on all shifts.

Interpretive Guideline

The intent of this regulation is to provide the facility with ongoing assessment information necessary to develop a care plan, to provide the appropriate care and services for each resident, and to modify the care plan and care/services based on the resident's status. The facility is expected to use resident observation and communication as the primary source of information when completing the assessment.

In addition to direct observation and communication with the resident, the facility should use a variety of other sources, including communication with licensed and non-licensed staff members on all shifts and may include discussions with the resident's physician, family members, or outside consultants and review of the resident's record.

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FED - C0389 - RESIDENT ASSESSMENT (483.20(b)(2))

Title RESIDENT ASSESSMENT (483.20(b)(2))

CFR 485.645(d)(6)

Type Standard

Regulation Definition	Interpretive Guideline
A facility must conduct a comprehensive assessment of a resident within 14 calendar days after admission, excluding readmissions in which there is no significant change in the resident's physical or mental condition. (For purposes of this section, "readmission" means a return to the facility following a temporary absence for hospitalization or for therapeutic leave.)	The intent of this regulation is to assess residents in a timely manner. "Admission" to the facility is defined as an initial stay or a return stay (not a readmission) in the facility. A "return stay" applies to those residents who are discharged without expectation that they will return to the facility, but who do return to the facility. A "readmission" is an expected return to the facility following a temporary absence for hospitalization, off-site visit or therapeutic leave. Items in (b)(2) of this section would include comprehensive assessments of a resident which were done within 14 days of admission; within 14 days of a significant change in the resident's physical or mental condition; or done on an annual review. These assessments need to be in the final discharge summary.

FED - C0390 - FREQUENCY OF ASSESSMENTS (483.20(b)(2))

Title FREQUENCY OF ASSESSMENTS (483.20(b)(2))

CFR 485.645(d)(6)

Type Standard

Regulation Definition	Interpretive Guideline
A facility must conduct a comprehensive assessment of a resident within 14 calendar days after the facility determines, or should have determined, that there has been a significant change in the resident's physical or mental condition (for purposes of this section, a "significant change" means a major	A "significant change" may include, but is not limited to, any of the following, or may be determined by a physician's decision if uncertainty exists. o Deterioration in two of more activities of daily living (ADLs), or any combination of deterioration in two or more areas of ADLs, communication, or cognitive abilities that appear permanent. For example, pronounced deterioration in function and communication following a stroke.

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decline or improvement in the resident's status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the resident's health status, and requires inter-disciplinary review or revision of the care plan, or both), or not less often than once every 12 months.

o Loss of ability to ambulate freely or to use hands to grasp small objects to feed or groom oneself, such as spoon, toothbrush, or comb. Temporary loss of ability, such as during an acute illness, is not included.
o Deterioration in behavior or mood, to the point where daily problems arise or relationships have become problematic and staff conclude that these changes in the resident's psychosocial status are not likely to improve without staff intervention.
o Deterioration in a resident's health status, where this change places the resident's life in danger (e.g., stroke, heart disease, metastatic cancer); where the change is associated with a serious clinical complication (e.g., initial development of a stage III pressure sore, prolonged delirious state, or recurrent decline in level of consciousness); or change that is associated with an initial diagnosis of a condition that is likely to affect the resident's physical, mental, or psychosocial well-being over a prolonged period of time (e.g., Alzheimer's disease or diabetes); or the onset of significant, unplanned weight loss (5% in the last 30 days, 10% in the last 180 days).

FED - C0395 - COMPREHENSIVE CARE PLANS (483.20(k)(1))

Title COMPREHENSIVE CARE PLANS (483.20(k)(1))

CFR 485.645(d)(6)

Type Standard

Regulation Definition

The facility must develop a comprehensive care plan for each resident that includes measurable objectives and timetables to meet a resident's medical, nursing, mental and psychosocial needs that are identified in the comprehensive assessment.

The care plan must describe the services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being as required under §483.25; and any services that would otherwise be required under §483.25 but are not provided due to the resident's exercise of rights under §483.10, including the right to refuse treatment under §483.10(b)(4).

Interpretive Guideline

An interdisciplinary team, in conjunction with the resident, resident's family, surrogate, or representative, as appropriate, should develop quantifiable objectives for the highest level of functioning the resident may be expected to attain, based on the comprehensive assessment. The care plan must reflect intermediate steps for each outcome objective if identification of those steps will enhance the resident's ability to meet his/her objectives. Facility staff will use these objectives to follow resident progress. Facilities may, for some residents, need to prioritize needed care. This should be noted in the clinical record or on the plan of care.

The requirements reflect the facility's responsibility to provide necessary care and services to attain or maintain the highest practicable physical, mental and psychosocial well being, in accordance with the comprehensive assessment and plan of care. In some cases, a resident may wish to refuse certain services or treatments that professional staff believe may be indicated to assist the resident in reaching his or her highest practicable level of well-being. Desires of the resident should be documented in the clinical record.

Survey Procedures
o Does the care plan address the needs, strengths and preferences identified in the comprehensive assessment?
o Is the care plan oriented toward preventing avoidable declines in functioning or functional levels?
o How does the care plan attempt to manage risk factors?

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o Does the care plan build on resident strengths?
o Do treatment objectives have measurable outcomes?
o Does the care plan reflect standards of current professional practice?
o Corroborate information regarding the resident's goals and wishes for treatment in the plan of care by interviewing residents; especially those identified as refusing treatment.
o Determine whether the facility has provided adequate information to the resident so that the resident was able to make an informed choice regarding treatment.
o If the resident has refused treatment, does the care plan reflect the facility's efforts to find alternative means to address the problem?

FED - C0396 - COMPREHENSIVE CARE PLANS (483.20(k)(2))

Title COMPREHENSIVE CARE PLANS (483.20(k)(2))

CFR 485.645(d)(6)

Type Standard

Regulation Definition

A comprehensive care plan must be developed within 7 days after the completion of the comprehensive assessment; prepared by an interdisciplinary team that includes the attending physician, a registered nurse with responsibility for the resident, and other appropriate staff in disciplines as determined by the resident's needs, and, to the extent practicable, the participation of the resident, the resident's family or the resident's legal representative; and periodically reviewed and revised by a team of qualified persons after each assessment.

Interpretive Guideline

"Interdisciplinary" means that professional disciplines, as appropriate, will work together to provide the greatest benefit to the resident. It does not mean that every goal must have an interdisciplinary approach. The mechanics of how the interdisciplinary team meets its responsibilities in developing an interdisciplinary care plan (e.g., a face-to-face meeting, teleconference, written communication) is at the discretion of the facility.

The physician must participate as part of the interdisciplinary team, and may arrange with the facility for alternative methods, other than attendance at care planning conferences, of providing his/her input, such as one-to-one discussions and conference calls.

The resident has the right to refuse specific treatments and to select among treatment options before the care plan is instituted. The facility should encourage residents, surrogates, and representatives to participate in care planning, including encouraging attendance at care planning conferences if they so desire.

Survey Procedures
o Was interdisciplinary expertise utilized to develop a plan to improve the resident's functional abilities?
- For example, did an occupational therapist design needed adaptive equipment or a speech therapist provide techniques to improve swallowing ability?
- Do the dietitian and the speech therapist determine, for example, the optimum textures and consistency for the resident's food that provide both a nutritionally adequate diet and effectively use oropharyngeal capabilities of the

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resident?
- Is there evidence of physician involvement in development of the care plan (e.g., presence at care planning meetings, conversations with team members concerning the care plan, conference calls)?
o In what ways does staff involve residents and families, surrogate, and/or representatives in care planning?
o Does staff make an effort to schedule care plan meetings at the best time of the day for residents and their families?
o Do facility staff attempt to make the process understandable to the resident/family?
o Is the care plan evaluated and revised as the resident's status changes?
o Ask in your resident interviews, "Have you had concerns or questions about your care and brought them to the attention of facility staff?" If yes, "What happened as a result?"

FED - C0397 - SERVICES PROVIDED (483.20(k)(3))

Title SERVICES PROVIDED (483.20(k)(3))

CFR 485.645(d)(6)

Type Standard

Regulation Definition

The services provided or arranged by the facility must meet professional standards of quality.

Interpretive Guideline

The intent of this regulation is to assure that persons providing services are qualified to do so, that the resident's plan of care is implemented, and that those services provided meet professional standards of quality and are provided by appropriate qualified persons (e.g., licensed, certified).

"Professional standards of quality" means services that are provided according to accepted standards of clinical practice. Standards may apply to care provided by a particular clinical discipline or in a specific clinical situation or setting. Standards regarding quality care practices may be published by a professional organization, licensing board, accreditation body or other regulatory agency. Recommended practices to achieve desired resident outcomes might also be found in clinical literature.

Survey Procedures
Question those practices that have a negative outcome or have a potential negative outcome.
o Do nurses notify physicians, as appropriate, and show evidence of discussions of acute medical problems?
o Are residents with acute conditions promptly hospitalized, as appropriate?
o Are there errors in medication administration?
o Is there evidence of assessment and care planning sufficient to meet the needs of newly admitted residents, prior to completion of the first comprehensive assessment and care plan?
o Are physician orders carried out, unless otherwise indicated by an advanced directive?
o Can staff describe the care, services and expected outcomes of the care they provide?

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FED - C0398 - SERVICES PROVIDED (483.20(k)(3))

Title SERVICES PROVIDED (483.20(k)(3))

CFR 485.645(d)(6)

Type Standard

Regulation Definition

The services provided or arranged by the facility must be provided by qualified persons in accordance with each resident's written plan of care.

Interpretive Guideline

FED - C0399 - DISCHARGE PLANNING (483.20(l))

Title DISCHARGE PLANNING (483.20(l))

CFR 485.645(d)(6)

Type Standard

Regulation Definition

When the facility anticipates discharge a resident must have a discharge summary that includes a recapitulation of the resident's stay; a final summary of the resident's status to include items in paragraph (b)(2) of this section, at the time of the discharge that is available for release to authorized persons and agencies, with the consent of the resident or legal representative; and a post-discharge plan of care that is developed with the participation of the resident and his or her family, which will assist the resident to adjust to his or her new living environment.

Interpretive Guideline

The intent of this regulation is to ensure appropriate discharge planning and communication of necessary information to the continuing care provider.

"Post discharge plan of care" means the discharge planning process that includes assessing continuing care needs and developing a plan designed to ensure the individual's needs will be met after discharge from the facility into the community.

When the facility "anticipates discharge" means that the discharge was not an emergency discharge (e.g., hospitalization for an acute condition), or due to the resident's death.

"Adjust to his or her living environment" means that the post discharge plan should describe the resident's and family's preferences for care, how the resident and family will access these services, and how care should be coordinated if continuing treatment involves multiple care givers. It should identify specific resident needs after discharge such as personal care, sterile dressings, and physical therapy, as well as describe resident/care giver education needs to ensure the resident/care giver is able to meet care needs after discharge.

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Survey Procedures
o Does the discharge summary have information pertinent to continuing care for the resident?
o Is there evidence of discharge planning in the records of discharged residents who had an anticipated discharge or those residents to be discharged shortly (e.g., in the next 7-14 days)?
o Do discharge plans address necessary post discharge care?
o Has the facility aided the resident and his/her family in locating and coordinating post discharge services?
o What types of pre-discharge preparation and education has the facility provided the resident and his/her family?

FED - C0400 - NUTRITION (483.25(i)(1))

Title NUTRITION (483.25(i)(1))

CFR 485.645(d)(9)

Type Standard

Regulation Definition

Based on a resident's comprehensive assessment, the facility must ensure that a resident maintains acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident's clinical condition demonstrates that this is not possible.

Interpretive Guideline

Parameters of nutritional status that are unacceptable include unplanned weight loss as well as other indices such as peripheral edema, cachexia and laboratory tests indicating malnourishment (e.g., serum albumin levels).

Weight: Since ideal body weight charts have not yet been validated for the institutionalized elderly, weight loss (or gain) is a guide in determining nutritional status. An analysis of weight loss or gain should be examined in light of the individual's former life style as well as the current diagnosis.

FED - C0401 - NUTRITION (483.25(i)(2))

Title NUTRITION (483.25(i)(2))

CFR 485.645(d)(9)

Type Standard

Regulation Definition

Based on a resident's comprehensive assessment, the facility must ensure that a resident receives a therapeutic diet when there is a nutritional problem.

Interpretive Guideline

Suggested parameters for evaluating significance of unplanned and undesired weight loss are:

Interval Significant Loss Severe Loss

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1 month	5%	Greater than 5%
3 months	7.5%	Greater than 7.5%
6 months	10%	Greater than 10%

The following formula determines percentage of loss:

% of body weight loss = ((usual weight - actual weight)/usual weight) x 100

In evaluating weight loss, consider the resident's usual weight through adult life; the assessment of potential for weight loss; and care plan for weight management. Also, was the resident on a calorie restricted diet, or if newly admitted and obese, and on a normal diet, are fewer calories provided than prior to admission? Was the resident edematous when initially weighed, and with treatment, no longer has edema? Has the resident refused food?

Suggested laboratory values are:

Albumin >60 yr.: 3.4 - 4.8 g/dl (good for examining marginal protein depletion)

Plasma Transferrin >60 yr.:180 - 380 g/dl. (Rises with iron deficiency anemia. More persistent indicator of protein status.)

Hemoglobin	Males:	14-17 g/dl
	Females:	12-15 g/dl
Hematocrit	Males:	41 - 53
	Females:	36 - 46
Potassium	3.5 - 5.0 mEq/L	
Magnesium	1.3 - 2.0 mEq/L	

Some laboratories may have different "normals". Determine range for the specific laboratory. Because some healthy elderly people have abnormal laboratory values, and because abnormal values can be expected in some disease processes, do not expect laboratory values to be within normal ranges for all residents. Consider abnormal values in conjunction with the resident's clinical condition and baseline normal values.
NOTE: There is no requirement that facilities order the tests referenced above.

Clinical Observations: Potential indicators of malnutrition are pale skin, dull eyes, swollen lips, swollen gums, and swollen and/or dry tongue with scarlet or magenta hue, poor skin turgor, cachexia, bilateral edema, and muscle

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wasting.

Risk factors for malnutrition are--
o Drug therapy that may contribute to nutritional deficiencies such as--
- Cardiac glycosides;
- Diuretics;
- Anti-inflammatory drugs;
- Antacids (antacid overuse);
- Laxatives (laxative overuse);
- Psychotropic drug overuse;
- Anticonvulsants;
- Antineoplastic drugs;
- Phenothiazines;
- Oral hypoglycemics;

o Poor oral health status or hygiene, eyesight, motor coordination, or taste alterations;
o Depression or dementia;
o Therapeutic or mechanically altered diet;
o Lack of access to culturally acceptable foods;
o Slow eating pace resulting in food becoming unpalatable, or in staff removing the tray before resident has finished eating; and
o Cancer.

Clinical conditions demonstrating that the maintenance of acceptable nutritional status may not be possible include, but are not limited to--
o Refusal to eat and refusal of other methods of nourishment;
o Advanced disease (i.e., cancer, malabsorption syndrome);
o Increased nutritional/caloric needs associated with pressure sores and wound healing (e.g., fractures, burns);
o Radiation or chemotherapy;
o Kidney disease, alcohol/drug abuse, chronic blood loss, hyperthyroidism;
o Gastrointestinal surgery; and
o Prolonged nausea, vomiting, diarrhea not relieved by treatment given according to accepted standards of practice.

"Therapeutic diet" means a diet ordered by a physician as part of treatment for a disease or clinical condition, to eliminate or decrease certain substances in the diet, (e.g., sodium) or to increase certain substances in the diet (e.g., potassium), or to provide food the resident is able to eat (e.g., a mechanically altered diet).

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Survey Procedures
o Determine if residents selected for a comprehensive review, or focused review as appropriate, have maintained acceptable parameters of nutritional status. Where indicated by the resident's medical status, have clinically appropriate therapeutic diets been prescribed?
o For sampled residents whose nutritional status is inadequate, do clinical conditions demonstrate that maintenance of inadequate nutritional status was unavoidable--
- Did the facility identify factors that put the resident at risk for malnutrition?
- What routine preventive measures and care did the resident receive to address unique risk factors for malnutrition (e.g., provision of an adequate diet with supplements or modifications as indicated by nutrient needs)?
- Were staff responsibilities for maintaining nutritional status clear, including monitoring the amount of food the resident is eating at each meal and offering substitutes?
- Was this care provided consistently?
- Were individual goals of the plan of care periodically evaluated and if not met, were alternative approaches considered or attempted?

FED - C0402 - SPECIALIZED REHAB SERVICES (483.45(a))

Title SPECIALIZED REHAB SERVICES (483.45(a))

CFR 485.645(d)(7)

Type Standard

Regulation Definition

If specialized rehabilitative services such as, but not limited to, physical therapy, speech-language pathology, occupational therapy, and mental health rehabilitative services for mental illness and mental retardation, are required in the resident's comprehensive plan of care, the facility must provide the required services; or obtain the required services from an outside resource (in accordance with §483.75(h) of this part) from a provider of specialized rehabilitative services.

Interpretive Guideline

The intent of this regulation is to assure that residents receive necessary specialized rehabilitative services as determined by the comprehensive assessment and care plan, to prevent avoidable physical and mental deterioration and to assist them in obtaining or maintaining their highest practicable level of functional and psychosocial well being.

Specialized rehabilitative services are considered a facility service and are included within the scope of facility services. They must be provided to residents who need them even when the services are not specifically enumerated in the State plan. No fee can be charged a Medicaid recipient for specialized rehabilitative services because they are covered facility services.

A facility is not obligated to provide specialized rehabilitative services if it does not have residents who require these services. If a resident develops a need for these services after admission, the facility must either provide the services, or, where appropriate, obtain the service from an outside resource.

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For a resident with mental illness (MI) or mental retardation (MR) to have his or her specialized needs met, the individual must receive all services necessary to assist the individual in maintaining or achieving as much independence and self determination as possible. Specialized services for mental illness or mental retardation refers to those services to be provided by the State which can only be delivered by personnel or programs other than those of the nursing facility (NF) because the overall level of NF services is not as intense as necessary to meet the individuals needs.

"Mental health rehabilitative services for MI and MR" refers to those services of lesser frequency or intensity to be implemented by all levels of nursing facility staff who come into contact with the resident who is mentally ill or who has mental retardation. These services are necessary regardless of whether or not they require additional services to be provided for or arranged by the State as specialized services.

Mental health rehabilitative services for MI and MR may include, but are not limited to
o Consistent implementation during the resident's daily routine and across settings, of systematic plans that are designed to change inappropriate behaviors;
o Drug therapy and monitoring of the effectiveness and side effects of medications which have been prescribed to change inappropriate behavior or to alter manifestations of psychiatric illness;
o Provision of a structured environment for those individuals who are determined to need such structure (e.g., structured socialization activities to diminish tendencies toward isolation and withdrawal);
o Development, maintenance and consistent implementation across settings of those programs designed to teach individuals the daily living skills they need to be more independent and self determining including, but not limited to, grooming, personal hygiene, mobility, nutrition, vocational skills, health, drug therapy, mental health education, money management, and maintenance of the living environment;
o Crisis intervention services;
o Individual, group, and family psychotherapy;
o Development of appropriate personal support networks; and
o Formal behavior modification progress.

Survey Procedures
Determine the extent of follow through with the comprehensive care plan. Verify from the chart that the resident is receiving frequency and type of therapy as outlined in the care plan.

1. Physical Therapy
o What did the facility do to improve the resident's muscle strength? The resident's balance?

o What did the facility do to determine if an assistive device would enable the resident to reach or maintain his/her highest practicable level of physical function?
o If the resident has an assistive device, is he/she encouraged to use it on a regular basis?
o What did the facility do to increase the amount of physical activity the resident could do (for example, the number of repetitions of an exercise, the distance walked)?
o What did the facility do to prevent or minimize contractures, which could lead to decreased mobility and increased risk of pressure ulcer occurrence?

2. Occupational Therapy
o What did the facility do to decrease the amount of assistance needed to perform a task?
o What did the facility do to decrease behavioral symptoms?
o What did the facility do to improve gross and fine motor coordination?
o What did the facility do to improve sensory awareness, visual-spatial awareness, and body integration?
o What did the facility do to improve memory, problem solving, attention span, and the ability to recognize safety hazards?

3. Speech, Language Pathology
o What did the facility do to improve auditory comprehension?
o What did the facility do to improve speech production?
o What did the facility do to improve expressive behavior?
o What did the facility do to improve the functional abilities of residents with moderate to severe hearing loss who have received an audiology evaluation?
o For the resident who cannot speak, did the facility assess for a communication board or an alternate means of communication?

4. Rehabilitative Services For MI and MR
o What did the facility do to decrease incidents of inappropriate behaviors, for individuals with MR, or behavioral symptoms for persons with MI? To increase appropriate behavior?
o What did the facility do to identify and treat the underlying factors behind tendencies toward isolation and withdrawal?
o What did the facility do to develop and maintain necessary daily living skills?
o How has the facility modified the training strategies it uses with its residents to account for the special learning needs of its residents with MI or MR?
o Questions to ask individuals with MI or MR--
- Who do you talk to when you have a problem or need something?
- What do you do when you feel happy? Sad? Can't sleep at night?
- In what activities are you involved, and how often?

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FED - C0403 - SPECIAL REHAB-QUALIFICATIONS (483.45(b))

Title SPECIAL REHAB-QUALIFICATIONS (483.45(b))

CFR 485.645(d)(7)

Type Standard

Regulation Definition

Specialized rehabilitative services must be provided under the written order of a physician by qualified personnel.

Interpretive Guideline

Specialized rehabilitative services are provided for individuals under a physician's order by a qualified professional. Once the assessment for specialized rehabilitative services is completed, a care plan must be developed, followed, and monitored by a licensed professional. Once a resident has met his or her care plan goals, a licensed professional can either discontinue treatment or initiate a maintenance program which either nursing or restorative aides will follow to maintain functional and physical status.

"Qualified personnel" means that professional staff are licensed, certified or registered to provide specialized therapy/rehabilitative services in accordance with applicable State laws. Health rehabilitative services for MI and MR must be implemented consistently by all staff unless the nature of the services is such that they are designated or required to be implemented only be licensed or credentialed personnel.

Survey Procedures
o Determine if there are any problems in quality of care related to maintaining or improving functional abilities. Determine if these problems are attributable in part to the qualifications of specialized rehabilitative services staff.
o Determine from the care plan and record that qualified personnel provide rehabilitative services under the written order of a physician. If a problem in a resident's rehabilitative care is identified that is related to the qualifications of the care providers, it might be necessary to validate the care provider's qualifications.
o If the facility does not employ professional staff who have experience working directly with or designing training or treatment programs to meet the needs of individuals with MI or MR, how has the facility arranged for the necessary direct or staff training services to be provided?

FED - C0404 - DENTAL SERVICES (483.55)

Title DENTAL SERVICES (483.55)

CFR 485.645(d)(8)

Type Standard

Aspen Federal Regulation Set: C 04.02 CRITICAL ACCESS HOSPITALS

Regulation Definition

The facility must assist residents in obtaining routine and 24-hour emergency dental care.

Interpretive Guideline

This requirement makes the facility directly responsible for the dental care needs of its residents. The facility must ensure that a dentist is available for residents. They can satisfy this requirement by employing a staff dentist or having a contract/arrangement with a dentist to provide services.

For Medicare and private pay residents, facilities are responsible for having the services available, but they may impose an additional charge for the services. Medicaid residents may not be charged.

For all residents of the facility, if they are unable to pay for needed dental services, the facility should attempt to find alternative funding sources or alternative service delivery systems so that the resident is able to maintain his/her highest practicable level of well being.

FED - C0405 - DENTAL SERVICES (483.55(a))

Title DENTAL SERVICES (483.55(a))

CFR 485.645(d)(8)

Type Standard

Regulation Definition

A facility must provide or obtain an outside resource, in accordance with §483.75(h) of this part, routine and emergency dental services to meet the needs of each resident. A facility may charge a Medicare resident an additional amount for routine and emergency dental services.

Interpretive Guideline

"Routine dental services" means an annual inspection of the oral cavity for signs of disease, diagnosis of dental disease, dental radiographs as needed, dental cleaning, fillings (new and repairs), minor dental plate adjustments, smoothing of broken teeth, and limited prosthodontic procedures (e.g., taking impressions for dentures and fitting dentures).

"Emergency dental services" includes services needed to treat an episode of acute pain in teeth, gums, or palate; broken, or otherwise damaged teeth, or any other problem of the oral cavity, appropriately treated by a dentist that requires immediate attention.

"Prompt referral' means, within reason, as soon as the dentures are lost or damaged. Referral does not mean that the resident must see the dentist at that time, but does mean that an appointment (referral) is made, or that the facility is aggressively working at replacing the dentures.

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FED - C0406 - DENTAL SERVICES (483.55(a))

Title DENTAL SERVICES (483.55(a))

CFR 485.645(d)(8)

Type Standard

Regulation Definition	Interpretive Guideline
A facility must, if necessary, assist the resident in making appointments; by arranging for transportation to and from the dentist's office; and promptly refer residents with lost or damaged dentures to a dentist.	Survey Procedures o Do residents selected for comprehensive or focused reviews, as appropriate, with dentures, use them? o Are residents missing teeth and may be in need of dentures? o Do sampled residents have problems eating and maintaining nutritional status because of poor oral health or oral hygiene? o Are resident's dentures intact? Properly fitted? NOTE: §483.55(b) Nursing Facilities does not usually apply to Medicare reimbursed swing-bed residents because Medicare swing-bed residents receive skilled nursing care comparable to services provided in a SNF not a NF. If a swing-bed resident is a NF level patient, apply standard §483.55(b) as appropriate.

FED - C0407 - DENTAL SERVICES (483.55(b))

Title DENTAL SERVICES (483.55(b))

CFR 485.645(d)(8)

Type Standard

Regulation Definition	Interpretive Guideline
The facility must provide or obtain from an outside resource, in accordance with §483.75(h) of this part, the following dental services to meet the needs of each resident: routine dental service (to the extent covered under the State plan); and emergency dental services.	"Routine dental services" means an annual inspection of the oral cavity for signs of disease, diagnosis of dental disease, dental radiographs as needed, dental cleaning, fillings (new and repairs), minor dental plate adjustments, smoothing of broken teeth, and limited prosthodontic procedures (e.g., taking impressions for dentures and fitting dentures). "Emergency dental services" includes services needed to treat an episode of acute pain in teeth, gums, or palate; broken, or otherwise damaged teeth, or any other problem of the oral cavity, appropriately treated by a dentist that requires immediate attention.

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"Prompt referral' means, within reason, as soon as the dentures are lost or damaged. Referral does not mean that the resident must see the dentist at that time, but does mean that an appointment (referral) is made, or that the facility is aggressively working at replacing the dentures.

FED - C0408 - DENTAL SERVICES (483.55(b))

Title DENTAL SERVICES (483.55(b))

CFR 485.645(d)(8)

Type Standard

Regulation Definition

The facility must, if necessary, assist the resident in making appointments; by arranging for transportation to and from the dentist's office; and must promptly refer residents with lost or damaged dentures to a dentist.

Interpretive Guideline

Survey Procedures
o Do residents selected for comprehensive or focused reviews, as appropriate, with dentures, use them?
o Are residents missing teeth and may be in need of dentures?
o Do sampled residents have problems eating and maintaining nutritional status because of poor oral health or oral hygiene?
o Are resident's dentures intact? Properly fitted?

FED - C0500 - PSYCH & REHAB DISTINCT PART UNITS - PSYCH

Title PSYCH & REHAB DISTINCT PART UNITS - PSYCH

CFR 485.647(a)(1)

Type Condition

Regulation Definition

If a CAH provides inpatient psychiatric services in a distinct part unit, the services furnished by the distinct part unit must comply with the hospital requirements specified in Subparts A, B, C, and D of Part 482 of this subchapter, the common requirements of §412.25(a)(2) through (f) of Part 412 of this chapter for hospital units excluded from the prospective payment systems, and the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Interpretive Guideline

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To be eligible to receive Medicare payments for psychiatric services as a distinct part unit, the facility provides no more than 10 beds in the distinct part unit.

The beds in the distinct part are excluded from the 25 inpatient-bed count limit specified in §485.620(a).

The average annual 96-hour length of stay requirement specified under §485.620(b) does not apply to the 10 beds in the distinct part units specified in paragraph (b)(1) of this section, and admissions and days of inpatient care in the distinct part units are not taken into account in determining the CAH's compliance with the limits on the number of beds and length of stay in §485.620.

FED - C0501 - ELIGIBILITY REQUIREMENTS

Title ELIGIBILITY REQUIREMENTS

CFR 485.647(b)

Type Standard

Regulation Definition

(1)To be eligible to receive Medicare payments for psychiatric or rehabilitation services as a distinct part unit, the facility provides no more than 10 beds in the distinct part unit.

(2) The beds in the distinct part are excluded from the 25 inpatient-bed count limit specified in §485.620(a).

(3)The average annual 96-hour length of stay requirement specified under §485.620(b) does not apply to the 10 beds in the distinct part units specified in paragraph (b)(1) of this section, and admissions and days of inpatient care in the distinct part units are not taken into account in determining the CAH's compliance with the limits on the number of beds and

Interpretive Guideline

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length of stay in §485.620.

FED - C0504 - ADMISSION CRITERIA (412.25(a)(2))

Title ADMISSION CRITERIA (412.25(a)(2))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
A psychiatric unit must have written admission criteria that are applied uniformly to both Medicare and non-Medicare patients.	

FED - C0505 - SEPARATE MEDICAL RECORDS (412.25(a)(3))

Title SEPARATE MEDICAL RECORDS (412.25(a)(3))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
A psychiatric unit must have admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available.	

FED - C0506 - POLICIES (412.25(a)(4))

Title POLICIES (412.25(a)(4))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
A psychiatric unit must have policies specifying that necessary	

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clinical information is transferred to the unit when a patient of the hospital is transferred to the unit.

FED - C0507 - STATE LICENSURE (412.25(a)(5))

Title STATE LICENSURE (412.25(a)(5))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
A psychiatric unit must meet applicable State licensure laws.	

FED - C0508 - UTILIZATION REVIEW (412.25(a)(6))

Title UTILIZATION REVIEW (412.25(a)(6))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
A psychiatric unit must have utilization review standards applicable for the type of care offered in the unit.	

FED - C0509 - SEPARATE BEDS (412.25(a)(7))

Title SEPARATE BEDS (412.25(a)(7))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
A psychiatric unit must have beds physically separate from (that is, not commingled with) the hospital's other beds.	

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FED - C0510 - FISCAL INTERMEDIARY (412.25(a)(8))

Title FISCAL INTERMEDIARY (412.25(a)(8))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
A psychiatric unit must be serviced by the same fiscal intermediary as the hospital.	Compliance with this requirement is determined by the FI.

FED - C0511 - SEPARATE COST CENTER (412.25(a)(9))

Title SEPARATE COST CENTER (412.25(a)(9))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
A psychiatric unit must be treated as a separate cost center for cost finding and apportionment purposes.	Compliance with this requirement is determined by the FI.

FED - C0512 - ACCOUNTING SYSTEM (412.25(a)(10))

Title ACCOUNTING SYSTEM (412.25(a)(10))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
A psychiatric unit must use an accounting system that properly allocates costs.	Compliance with this requirement is determined by the FI.

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FED - C0513 - MAINTAIN ALLOCATION DATA (412.25(a)(11))

Title MAINTAIN ALLOCATION DATA (412.25(a)(11))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
A psychiatric unit must maintain adequate statistical data to support the basis of allocation.	Compliance with this requirement is determined by the FI.

FED - C0514 - FISCAL PERIOD (412.25(a)(12))

Title FISCAL PERIOD (412.25(a)(12))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
A psychiatric unit must report its costs in the hospital's cost report covering the same fiscal period and using the same method of apportionment as the hospital.	Compliance with this requirement is determined by the FI.

FED - C0515 - FULLY EQUIPPED AND STAFFED (412.25(a)(13))

Title FULLY EQUIPPED AND STAFFED (412.25(a)(13))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
A psychiatric unit must, as of the first day of the first cost reporting period for which all other exclusion requirements are met, be fully equipped and staffed and capable of providing	

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hospital inpatient psychiatric care, regardless of whether there are any inpatients in the unit on that date.

FED - C0516 - INCREASE IN SIZE (412.25(b)(1))

Title INCREASE IN SIZE (412.25(b)(1))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
For purposes of exclusions from the prospective payment systems under this section, changes in the number of beds and square footage considered to be part of each excluded unit are allowed as specified in paragraphs (b)(1) through (b)(3) of this section. Except as described in paragraph (b)(3) of this section, the number of beds and square footage of an excluded unit may be increased only at the start of a cost reporting period.	Compliance with this requirement is determined by the FI.

FED - C0517 - DECREASE IN SIZE (412.25(b)(2))

Title DECREASE IN SIZE (412.25(b)(2))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
Except as described in paragraph (b)(3) of this section, the number of beds and square footage of an excluded unit may be decreased at any time during a cost reporting period if the hospital notifies its fiscal intermediary and the CMS Regional Office in writing of the planned decrease at least 30 days before the date of the decrease, and maintains the information needed to accurately determine costs that are attributable to	Compliance with this requirement is determined by the FI.

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the excluded unit. Any decrease in the number of beds or square footage considered to be part of an excluded unit made during a cost reporting period must remain in effect for the rest of that cost reporting period.

FED - C0518 - RELOCATION OF A UNIT (412.25(b)(3))

Title RELOCATION OF A UNIT (412.25(b)(3))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The number of beds in an excluded unit may be decreased, and the square footage considered to be part of the unit may be either increased or decreased, at any time, if these changes are made necessary by relocation of a unit; tTo permit construction or renovation necessary for compliance with changes in Federal, State, or local law affecting the physical facility; or because of catastrophic events such as fires, floods, earthquakes, or tornadoes.	Compliance with this requirement is determined by the FI.

FED - C0519 - CHANGES IN STATUS OF A UNIT (412.25(c)(1))

Title CHANGES IN STATUS OF A UNIT (412.25(c)(1))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
For purposes of exclusions from the prospective payment systems under this section, the status of each hospital unit (excluded or not excluded) is determined as specified in paragraphs (c)(1) and (c)(2) of this section. The status of a hospital unit may be changed from not	Compliance with this requirement is determined by the FI.

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excluded to excluded only at the start of the cost reporting period. If a unit is added to a hospital after the start of a cost reporting period, it cannot be excluded from the prospective payment systems before the start of a hospital's next cost reporting period.

FED - C0520 - 30-DAY NOTICE (412.25(c)(2))

Title 30-DAY NOTICE (412.25(c)(2))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The status of a hospital unit may be changed from excluded to not excluded at any time during a cost reporting period, but only if the hospital notifies the fiscal intermediary and the CMS Regional Office in writing of the change at least 30 days before the date of the change, and maintains the information needed to accurately determine costs that are or are not attributable to the excluded unit. A change in the status of a unit from excluded to not excluded that is made during a cost reporting period must remain in effect for the rest of that cost reporting period.	Compliance with this requirement is determined by the FI.

FED - C0521 - NUMBER OF UNITS (412.25(d))

Title NUMBER OF UNITS (412.25(d))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
Each hospital may have only one unit of each type (psychiatric or rehabilitation) excluded from the prospective payment systems.	Compliance with this requirement is determined by the FI.

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FED - C0522 - SATELLITES-DEFINITION (412.25(e)(1))

Title SATELLITES-DEFINITION (412.25(e)(1))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
For purposes of paragraphs (e)(2) through (e)(4) of this section, a satellite facility is a part of a hospital unit that provides inpatient services in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital.	Compliance with this requirement is determined by the FI.

FED - C0523 - SATELLITES-NUMBER OF BEDS (412.25(e)(2))

Title SATELLITES-NUMBER OF BEDS (412.25(e)(2))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
Except as provided in paragraphs (e)(3) and (e)(5) of this section, effective for cost reporting periods beginning on or after October 1, 1999, a hospital that has a satellite facility must meet the following criteria in order to be excluded from the acute care hospital inpatient prospective payment systems for any period. In the case of a unit excluded from the prospective payment systems for the most recent cost reporting period beginning before October 1, 1997, the unit's number of State-licensed and Medicare-certified beds, including those at the satellite facility, does not exceed the unit's number of State-licensed and Medicare-certified beds on the last day of the unit's last	Compliance with this requirement is determined by the FI.

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cost reporting period beginning before October 1, 1997.

FED - C0524 - SATELLITES-ADMISSION CRITERIA (412.25(e)(2))

Title SATELLITES-ADMISSION CRITERIA (412.25(e)(2))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The satellite facility independently complies with the requirements under §412.27(a).	Compliance with this requirement is determined by the FI.

FED - C0525 - SATELLITES-INDEPENDENT STAFF (412.25(e)(2))

Title SATELLITES-INDEPENDENT STAFF (412.25(e)(2))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The satellite facility, effective for cost reporting periods beginning on or after October 1, 2002, is not under the control of the governing body or chief executive officer of the hospital in which it is located, and it furnishes inpatient care through the use of medical personnel who are not under the control of the medical staff or chief medical officer of the hospital in which it is located.	Compliance with this requirement is determined by the FI.

FED - C0526 - SATELLITES-SEPARATE RECORDS (412.25(e)(2))

Title SATELLITES-SEPARATE RECORDS (412.25(e)(2))

CFR 485.647(a)(1)

Type Standard

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Regulation Definition	Interpretive Guideline
The satellite facility maintains admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available.	

FED - C0527 - SATELLITES-SEPARATE BEDS (412.25(e)(2))

Title SATELLITES-SEPARATE BEDS (412.25(e)(2))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The satellite facility has beds that are physically separate from (that is, not commingled with) the beds of the hospital in which it is located.	

FED - C0528 - SATELLITES-FISCAL INTERMEDIARY (412.25(e)(2))

Title SATELLITES-FISCAL INTERMEDIARY (412.25(e)(2))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The satellite facility is serviced by the same fiscal intermediary as the hospital unit of which it is a part.	Compliance with this requirement is determined by the FI.

FED - C0529 - SATELLITES-COST CENTER (412.25(e)(2))

Title SATELLITES-COST CENTER (412.25(e)(2))

CFR 485.647(a)(1)

Type Standard

Aspen Federal Regulation Set: C 04.02 CRITICAL ACCESS HOSPITALS

Regulation Definition	Interpretive Guideline
The satellite facility is treated as a separate cost center of the hospital unit of which it is a part.	Compliance with this requirement is determined by the FI.

FED - C0530 - SATELLITES-MAINTAIN DATA (412.25(e)(2))

Title SATELLITES-MAINTAIN DATA (412.25(e)(2))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The satellite facility for cost reporting and apportionment purposes, uses an accounting system that properly allocates costs and maintains adequate statistical data to support the basis of allocation.	Compliance with this requirement is determined by the FI.

FED - C0531 - SATELLITES-FISCAL PERIOD (412.25(e)(2))

Title SATELLITES-FISCAL PERIOD (412.25(e)(2))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The satellite facility reports its costs on the cost report of the hospital of which it is a part, covering the same fiscal period and using the same method of apportionment as the hospital of which it is a part.	Compliance with this requirement is determined by the FI.

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FED - C0532 - SATELLITE FACILITIES (412.25(e)(3))

Title SATELLITE FACILITIES (412.25(e)(3))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
Except as specified in paragraph (e)(4) of this section, the provisions of paragraph (e)(2) of this section do not apply to any unit structured as a satellite facility on September 30, 1999, and excluded from the prospective payment systems on that date, to the extent the unit continues operating under the same terms and conditions, including the number of beds and square footage considered to be part of the unit, in effect on September 30, 1999.	Compliance with this requirement is determined by the FI.

FED - C0533 - SATELLITES-RELOCATION (412.25(e)(4))

Title SATELLITES-RELOCATION (412.25(e)(4))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
In applying the provisions of paragraph (e)(3) of this section, any unit structured as a satellite facility as of September 30, 1999, may increase or decrease the square footage of the satellite facility or may decrease the number of beds in the satellite facility at any time, if these changes are made necessary by relocation of the facility to permit construction or renovation necessary for compliance with changes in Federal, State, or local law affecting the physical facility; or because of catastrophic events such as fires, floods, earthquakes, or tornadoes.	Compliance with this requirement is determined by the FI.

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FED - C0535 - CHANGES IN CLASSIFICATION (412.25(f))

Title CHANGES IN CLASSIFICATION (412.25(f))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
For purposes of exclusions from the prospective payment system under this section, the classification of a hospital unit is effective for the unit's entire cost reporting period. Any changes in the classification of a hospital unit is made only at the start of a cost reporting period.	Compliance with this requirement is determined by the FI.

FED - C0547 - ADMISSIONS (412.27(a))

Title ADMISSIONS (412.27(a))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
A psychiatric unit must admit only patients whose admission to the unit is required for active treatment, of an intensity that can be provided appropriately only in an inpatient hospital setting, of a psychiatric principal diagnosis that is listed in the Third Edition of the American Psychiatric Association's Diagnostic and Statistical Manual, or in Chapter Five ("Mental Disorders") of the International Classification of Diseases, Ninth Revision, Clinical Modification.	

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FED - C0548 - QUALIFIED PERSONNEL (412.27(b))

Title QUALIFIED PERSONNEL (412.27(b))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
A psychiatric unit must furnish, through the use of qualified personnel, psychological services, social work services, psychiatric nursing, occupational therapy, and recreational therapy.	

FED - C0549 - MEDICAL RECORDS (412.27(c)(1))

Title MEDICAL RECORDS (412.27(c)(1))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
A psychiatric unit must maintain medical records that permit determination of the degree and intensity of the treatment provided to individuals who are furnished services in the unit, and that meet the following requirement. Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the inpatient is treated in the unit.	

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FED - C0550 - INPATIENT LEGAL STATUS (412.27(c)(1))

Title INPATIENT LEGAL STATUS (412.27(c)(1))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
Identification data must include the inpatient's legal status.	

FED - C0551 - ADMITTING DIAGNOSIS (412.27(c)(1))

Title ADMITTING DIAGNOSIS (412.27(c)(1))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
A provisional or admitting diagnosis must be made on every inpatient at the time of admission, and must include the diagnoses of every inpatient at the time of admission, and must include the diagnoses of intercurrent diseases as well as the psychiatric diagnoses.	

FED - C0552 - REASONS FOR ADMISSION (412.27(c)(1))

Title REASONS FOR ADMISSION (412.27(c)(1))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The reasons for admission must be clearly documented as stated by the inpatient or others significantly involved, or both.	

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FED - C0553 - SOCIAL SERVICE RECORDS (412.27(c)(1))

Title SOCIAL SERVICE RECORDS (412.27(c)(1))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The social service records, including reports of interviews with inpatients, family members, and others must provide an assessment of home plans and family attitudes, and community resource contacts as well as a social history.	

FED - C0554 - NEUROLOGICAL EXAMINATION (412.27(c)(1))

Title NEUROLOGICAL EXAMINATION (412.27(c)(1))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
When indicated, a complete neurological examination must be recorded at the time of the admission physical examination.	

FED - C0555 - PSYCHIATRIC EVALUATION (412.27(c)(2))

Title PSYCHIATRIC EVALUATION (412.27(c)(2))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
Each inpatient must receive a psychiatric evaluation that must be completed within 60 hours of admission.	

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FED - C0556 - MEDICAL HISTORY (412.27(c)(2))

Title MEDICAL HISTORY (412.27(c)(2))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
Each inpatient must receive a psychiatric evaluation that must include a medical history.	

FED - C0557 - MENTAL STATUS (412.27(c)(2))

Title MENTAL STATUS (412.27(c)(2))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
Each inpatient must receive a psychiatric evaluation that must contain a record of mental status.	

FED - C0558 - ONSET OF ILLNESS (412.27(c)(2))

Title ONSET OF ILLNESS (412.27(c)(2))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
Each inpatient must receive a psychiatric evaluation that must note the onset of illness and the circumstances leading to admission.	

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FED - C0559 - ATTITUDES AND BEHAVIOR (412.27(c)(2))

Title ATTITUDES AND BEHAVIOR (412.27(c)(2))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
Each inpatient must receive a psychiatric evaluation that must describe attitudes and behavior.	

FED - C0560 - INTELLECTUAL FUNCTIONING (412.27(c)(2))

Title INTELLECTUAL FUNCTIONING (412.27(c)(2))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
Each inpatient must receive a psychiatric evaluation that must estimate intellectual functioning, memory functioning, and orientation.	

FED - C0561 - INPATIENT'S ASSETS (412.27(c)(2))

Title INPATIENT'S ASSETS (412.27(c)(2))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
Each inpatient must receive a psychiatric evaluation that must include an inventory of the inpatient's assets in descriptive, not interpretative fashion.	

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FED - C0562 - TREATMENT PLAN-DIAGNOSIS (412.27(c)(3))

Title TREATMENT PLAN-DIAGNOSIS (412.27(c)(3))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
Each inpatient must have an individual comprehensive treatment plan that must be based on an inventory of the inpatient's strengths and disabilities. The written plan must include a substantiated diagnosis.	

FED - C0563 - TREATMENT PLAN-GOALS (412.27(c)(3))

Title TREATMENT PLAN-GOALS (412.27(c)(3))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
Each inpatient must have an individual comprehensive treatment plan that must be based on an inventory of the inpatient's strengths and disabilities. The written plan must include short-term and long-term goals.	

FED - C0564 - TREATMENT PLAN-MODALITIES (412.27(c)(3))

Title TREATMENT PLAN-MODALITIES (412.27(c)(3))

CFR 485.647(a)(1)

Type Standard

Aspen Federal Regulation Set: C 04.02 CRITICAL ACCESS HOSPITALS

Regulation Definition

Each inpatient must have an individual comprehensive treatment plan that must be based on an inventory of the inpatient's strengths and disabilities. The written plan must include the specific treatment modalities utilized.

Interpretive Guideline

FED - C0565 - TREATMENT PLAN-TEAM (412.27(c)(3))

Title TREATMENT PLAN-TEAM (412.27(c)(3))

CFR 485.647(a)(1)

Type Standard

Regulation Definition

Each inpatient must have an individual comprehensive treatment plan that must be based on an inventory of the inpatient's strengths and disabilities. The written plan must include the responsibilities of each member of the treatment team.

Interpretive Guideline

FED - C0566 - TREATMENT PLAN-DOCUMENTATION (412.27(c)(3))

Title TREATMENT PLAN-DOCUMENTATION (412.27(c)(3))

CFR 485.647(a)(1)

Type Standard

Regulation Definition

Each inpatient must have an individual comprehensive treatment plan that must be based on an inventory of the inpatient's strengths and disabilities. The written plan must include adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out.

Interpretive Guideline

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FED - C0567 - TREATMENT PLAN-THERAPY (412.27(c)(3))

Title TREATMENT PLAN-THERAPY (412.27(c)(3))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The treatment received by the inpatient must be documented in such a way as to assure that all active therapeutic efforts are included.	

FED - C0568 - PROGRESS NOTES-MD/DO (412.27(c)(4))

Title PROGRESS NOTES-MD/DO (412.27(c)(4))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
Progress notes must be recorded by the doctor of medicine or osteopathy responsible for the care of the inpatient.	

FED - C0569 - PROGRESS NOTES-NURSE (412.27(c)(4))

Title PROGRESS NOTES-NURSE (412.27(c)(4))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
Progress notes must be recorded by a nurse.	

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FED - C0570 - PROGRESS NOTES-SOCIAL WORKER (412.27(c)(4))

Title PROGRESS NOTES-SOCIAL WORKER (412.27(c)(4))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
Progress notes must be recorded by the social worker.	

FED - C0571 - PROGRESS NOTES-OTHERS (412.27(c)(4))

Title PROGRESS NOTES-OTHERS (412.27(c)(4))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
Progress notes must be recorded by others significantly involved in active treatment modalities, when appropriate.	

FED - C0572 - PROGRESS NOTES-FREQUENCY (412.27(c)(4))

Title PROGRESS NOTES-FREQUENCY (412.27(c)(4))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The frequency of progress notes is determined by the condition of the inpatient but must be recorded at least weekly for the first two months and at least once a month thereafter.	

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FED - C0573 - PROGRESS NOTES-REVISIONS (412.27(c)(4))

Title PROGRESS NOTES-REVISIONS (412.27(c)(4))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The progress notes must contain recommendations for revisions in the treatment plan as indicated as well as precise assessment of the inpatient's progress in accordance with the original or revised treatment plan.	

FED - C0574 - DISCHARGE SUMMARY (412.27(c)(5))

Title DISCHARGE SUMMARY (412.27(c)(5))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The record of each patient who has been discharged must have a discharge summary that includes a recapitulation of the inpatient's hospitalization in the unit.	

FED - C0575 - DISCHARGE PLANNING-FOLLOW-UP (412.27(c)(5))

Title DISCHARGE PLANNING-FOLLOW-UP (412.27(c)(5))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The record of each patient who has been discharged must have	

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recommendations from appropriate services concerning follow-up or aftercare.

FED - C0576 - CONDITION ON DISCHARGE (412.27(c)(5))

Title CONDITION ON DISCHARGE (412.27(c)(5))

CFR 485.647(a)(1)

Type Standard

Regulation Definition

The record of each patient who has been discharged must have a brief summary of the patient's condition on discharge.

Interpretive Guideline

FED - C0577 - ADEQUATE NUMBER OF STAFF (412.27(d))

Title ADEQUATE NUMBER OF STAFF (412.27(d))

CFR 485.647(a)(1)

Type Standard

Regulation Definition

A psychiatric unit must meet special staff requirements in that the unit must have adequate numbers of qualified professional and supportive staff to evaluate inpatients, formulate written, individualized, comprehensive treatment plans, provide active treatment measures and engage in discharge planning.

Interpretive Guideline

FED - C0578 - ADEQUATE TYPES OF PERSONNEL (412.27(d)(1))

Title ADEQUATE TYPES OF PERSONNEL (412.27(d)(1))

CFR 485.647(a)(1)

Type Standard

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Regulation Definition

The psychiatric unit must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to evaluate inpatients; formulate written, individualized, comprehensive treatment plans; provide active treatment measures; and engage in discharge planning.

Interpretive Guideline

FED - C0579 - DIRECTOR (412.27(d)(2))

Title DIRECTOR (412.27(d)(2))

CFR 485.647(a)(1)

Type Standard

Regulation Definition

Inpatient psychiatric services must be under the supervision of a clinical director, service chief, or equivalent who is qualified to provide the leadership required for an intensive treatment program.

Interpretive Guideline

FED - C0580 - MEDICAL DOCTORS (412.27(d)(2))

Title MEDICAL DOCTORS (412.27(d)(2))

CFR 485.647(a)(1)

Type Standard

Regulation Definition

The number and qualifications of doctors of medicine and osteopathy must be adequate to provide essential psychiatric services.

Interpretive Guideline

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FED - C0581 - CLINICAL DIRECTOR (412.27(d)(2))

Title CLINICAL DIRECTOR (412.27(d)(2))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The clinical director, service chief, or equivalent must meet the training and experience requirements for examination by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry.	

FED - C0582 - QUALITY OF SERVICES (412.27(d)(2))

Title QUALITY OF SERVICES (412.27(d)(2))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The clinical director must monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff.	

FED - C0583 - NURSING DIRECTOR (412.27(d)(3))

Title NURSING DIRECTOR (412.27(d)(3))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The unit must have a qualified director of psychiatric nursing	

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services.

FED - C0584 - NUMBERS OF NURSING STAFF (412.27(d)(3))

Title NUMBERS OF NURSING STAFF (412.27(d)(3))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
In addition to the director of nursing, there must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide nursing care necessary under each inpatient's active treatment program and to maintain progress notes on each inpatient.	

FED - C0585 - DON QUALIFICATIONS (412.27(d)(3))

Title DON QUALIFICATIONS (412.27(d)(3))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The director of psychiatric nursing services must be a registered nurse who has a master's degree in psychiatric or mental health nursing, or its equivalent, from a school of nursing accredited by the National League for Nursing, or be qualified by education and experience in the care of the mentally ill.	

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FED - C0586 - DON COMPETENCE (412.27(d)(3))

Title DON COMPETENCE (412.27(d)(3))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The director of psychiatric nursing services must demonstrate competence to participate in interdisciplinary formulation of individual treatment plans; to give skilled nursing care and therapy; and to direct, monitor, and evaluate the nursing care furnished.	

FED - C0587 - RN REQUIREMENT (412.27(d)(3))

Title RN REQUIREMENT (412.27(d)(3))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The staffing pattern must ensure the availability of a registered nurse 24 hours each day.	

FED - C0588 - STAFF FOR NURSING CARE (412.27(d)(3))

Title STAFF FOR NURSING CARE (412.27(d)(3))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
There must be adequate numbers of registered nurses, licensed	

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practical nurses, and mental health workers to provide the nursing care necessary under each inpatient's active treatment program.

FED - C0589 - PSYCHOLOGICAL SERVICES (412.27(d)(4))

Title PSYCHOLOGICAL SERVICES (412.27(d)(4))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The unit must provide or have available psychological services to meet the needs of the inpatients.	

FED - C0590 - PSYCHOLOGICAL SERVICES (412.27(d)(4))

Title PSYCHOLOGICAL SERVICES (412.27(d)(4))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The psychological services must be furnished in accordance with acceptable standards of practice, service objectives, and established policies and procedures.	

FED - C0591 - SOCIAL SERVICES DIRECTOR (412.27(d)(5))

Title SOCIAL SERVICES DIRECTOR (412.27(d)(5))

CFR 485.647(a)(1)

Type Standard

Aspen Federal Regulation Set: C 04.02 CRITICAL ACCESS HOSPITALS

Regulation Definition

There must be a director of social services who monitors and evaluates the quality and appropriateness of social services furnished.

Interpretive Guideline

FED - C0592 - SOCIAL SERVICES (412.27(d)(5))

Title SOCIAL SERVICES (412.27(d)(5))

CFR 485.647(a)(1)

Type Standard

Regulation Definition

The social services must be furnished in accordance with accepted standards of practice and established policies and procedures.

Interpretive Guideline

FED - C0593 - SOCIAL SERVICE RESPONSIBILITIES(412.27(d)(5))

Title SOCIAL SERVICE RESPONSIBILITIES(412.27(d)(5))

CFR 485.647(a)(1)

Type Standard

Regulation Definition

Social service staff responsibilities must include, but are not limited to, participating in discharge planning, arranging for follow-up care, and developing mechanisms for exchange of appropriate information with sources outside the hospital.

Interpretive Guideline

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FED - C0594 - THERAPEUTIC ACTIVITIES (412.27(d)(6))

Title THERAPEUTIC ACTIVITIES (412.27(d)(6))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The unit must provide a therapeutic activities program.	

FED - C0595 - ACTIVITIES PROGRAM (412.27(d)(6))

Title ACTIVITIES PROGRAM (412.27(d)(6))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The therapeutic activities program must be appropriate to the needs and interests of inpatients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning.	

FED - C0596 - ACTIVITIES STAFF (412.27(d)(6))

Title ACTIVITIES STAFF (412.27(d)(6))

CFR 485.647(a)(1)

Type Standard

Regulation Definition	Interpretive Guideline
The number of qualified therapeutic activities therapists, support personnel, and consultants must be adequate to provide comprehensive therapeutic activities consistent with	

each inpatient's active
treatment program.

FED - C0700 - PSYCH & REHAB DISTINCT PART UNITS - REHAB

Title PSYCH & REHAB DISTINCT PART UNITS - REHAB

CFR 485.647(a)(2)

Type Condition

Regulation Definition	Interpretive Guideline
If a CAH provides inpatient rehabilitation services in a distinct part unit, the services furnished by the distinct part unit must comply with the hospital requirements specified in Subparts A, B, C, and D of Part 482 of this subchapter, the common requirements of §412.25(a)(2) through (f) of Part 412 of this chapter for hospital units excluded from the prospective payment systems, and the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.	

FED - C0701 - ELIGIBILITY REQUIREMENTS

Title ELIGIBILITY REQUIREMENTS

CFR 485.647(b)

Type Standard

Regulation Definition	Interpretive Guideline
(1) To be eligible to receive Medicare payments for psychiatric or rehabilitation services as a distinct part unit, the facility provides no more than 10 beds in the distinct part unit. (2) The beds in the distinct part are excluded from the 25 inpatient-bed count limit specified in §485.620(a).	

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(3) The average annual 96-hour length of stay requirement specified under §485.620(b) does not apply to the 10 beds in the distinct part units specified in paragraph (b)(1) of this section, and admissions and days of inpatient care in the distinct part units are not taken into account in determining the CAH's compliance with the limits on the number of beds and length of stay in §485.620.

FED - C0704 - ADMISSION CRITERIA (412.25(a)(2))

Title ADMISSION CRITERIA (412.25(a)(2))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
A rehabilitation unit must have written admission criteria that are applied uniformly to both Medicare and non-Medicare patients.	

FED - C0705 - SEPARATE MEDICAL RECORDS (412.25(a)(3))

Title SEPARATE MEDICAL RECORDS (412.25(a)(3))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
A rehabilitation unit must have admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available.	

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FED - C0706 - POLICIES (412.25(a)(4))

Title POLICIES (412.25(a)(4))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
A rehabilitation unit must have policies specifying that necessary clinical information is transferred to the unit when a patient of the hospital is transferred to the unit.	

FED - C0707 - STATE LICENSURE (412.25(a)(5))

Title STATE LICENSURE (412.25(a)(5))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
A rehabilitation unit must meet applicable State licensure laws.	

FED - C0708 - UTILIZATION REVIEW (412.25(a)(6))

Title UTILIZATION REVIEW (412.25(a)(6))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
A rehabilitation unit must have utilization review standards applicable for the type of care offered in the unit.	

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FED - C0709 - SEPARATE BEDS (412.25(a)(7))

Title SEPARATE BEDS (412.25(a)(7))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
A rehabilitation unit must have beds physically separate from (that is, not commingled with) the hospital's other beds.	

FED - C0710 - FISCAL INTERMEDIARY (412.25(a)(8))

Title FISCAL INTERMEDIARY (412.25(a)(8))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
A rehabilitation unit must be serviced by the same fiscal intermediary as the hospital.	Compliance with this requirement is determined by the FI.

FED - C0711 - SEPARATE COST CENTER (412.25(a)(9))

Title SEPARATE COST CENTER (412.25(a)(9))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
A rehabilitation unit must be treated as a separate cost center for cost finding and apportionment purposes.	Compliance with this requirement is determined by the FI.

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FED - C0712 - ACCOUNTING SYSTEM (412.25(a)(10))

Title ACCOUNTING SYSTEM (412.25(a)(10))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
A rehabilitation unit must use an accounting system that properly allocates costs.	Compliance with this requirement is determined by the FI.

FED - C0713 - MAINTAIN ALLOCATION DATA (412.25(a)(11))

Title MAINTAIN ALLOCATION DATA (412.25(a)(11))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
A rehabilitation unit must maintain adequate statistical data to support the basis of allocation.	Compliance with this requirement is determined by the FI.

FED - C0714 - FISCAL PERIOD (412.25(a)(12))

Title FISCAL PERIOD (412.25(a)(12))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
A rehabilitation unit must report its costs in the hospital's cost report covering the same fiscal period and using the same method of apportionment as the hospital.	Compliance with this requirement is determined by the FI.

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FED - C0715 - FULLY EQUIPPED AND STAFFED (412.25(a)(13))

Title FULLY EQUIPPED AND STAFFED (412.25(a)(13))

CFR 485.647(a)(2)

Type Standard

Regulation Definition

A rehabilitation unit must, as of the first day of the first cost reporting period for which all other exclusion requirements are met, be fully equipped and staffed and capable of providing hospital inpatient rehabilitation care, regardless of whether there are any inpatients in the unit on that date.

Interpretive Guideline

FED - C0716 - INCREASE IN SIZE (412.25(b)(1))

Title INCREASE IN SIZE (412.25(b)(1))

CFR 485.647(a)(2)

Type Standard

Regulation Definition

For purposes of exclusions from the prospective payment systems under this section, changes in the number of beds and square footage considered to be part of each excluded unit are allowed as specified in paragraphs (b)(1) through (b)(3) of this section.

Except as described in paragraph (b)(3) of this section, the number of beds and square footage of an excluded unit may be increased only at the start of a cost reporting period.

Interpretive Guideline

Compliance with this requirement is determined by the FI.

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FED - C0717 - DECREASE IN SIZE (412.25(b)(2))

Title DECREASE IN SIZE (412.25(b)(2))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
Except as described in paragraph (b)(3) of this section, the number of beds and square footage of an excluded unit may be decreased at any time during a cost reporting period if the hospital notifies its fiscal intermediary and the CMS Regional Office in writing of the planned decrease at least 30 days before the date of the decrease, and maintains the information needed to accurately determine costs that are attributable to the excluded unit. Any decrease in the number of beds or square footage considered to be part of an excluded unit made during a cost reporting period must remain in effect for the rest of that cost reporting period.	Compliance with this requirement is determined by the FI.

FED - C0718 - RELOCATION OF A UNIT (412.25(b)(3))

Title RELOCATION OF A UNIT (412.25(b)(3))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
The number of beds in an excluded unit may be decreased, and the square footage considered to be part of the unit may be either increased or decreased, at any time, if these changes are made necessary by relocation of a unit to permit construction or renovation necessary for compliance with changes in Federal, State, or local law affecting the physical facility; or because of catastrophic events such as fires, floods,	Compliance with this requirement is determined by the FI.

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earthquakes, or tornadoes.

FED - C0719 - CHANGES IN STATUS OF A UNIT (412.25(c)(1))

Title CHANGES IN STATUS OF A UNIT (412.25(c)(1))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
For purposes of exclusions from the prospective payment systems under this section, the status of each hospital unit (excluded or not excluded) is determined as specified in paragraphs (c)(1) and (c)(2) of this section. The status of a hospital unit may be changed from not excluded to excluded only at the start of the cost reporting period. If a unit is added to a hospital after the start of a cost reporting period, it cannot be excluded from the prospective payment systems before the start of a hospital's next cost reporting period.	Compliance with this requirement is determined by the FI.

FED - C0720 - 30-DAY NOTICE (412.25(c)(2))

Title 30-DAY NOTICE (412.25(c)(2))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
The status of a hospital unit may be changed from excluded to not excluded at any time during a cost reporting period, but only if he hospital notifies the fiscal intermediary and the CMS Regional Office in writing of the change at least 30 days before the date of the change, and maintains the information needed to accurately determine costs that are or are not	Compliance with this requirement is determined by the FI.

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attributable to the excluded unit. A change in the status of a unit from excluded to not excluded that is made during a cost reporting period must remain in effect for the rest of that cost reporting period.

FED - C0721 - NUMBER OF UNITS (412.25(d))

Title NUMBER OF UNITS (412.25(d))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
Each hospital may have only one unit of each type (psychiatric or rehabilitation) excluded from the prospective payment systems.	Compliance with this requirement is determined by the FI.

FED - C0722 - SATELLITES-DEFINITION (412.25(e)(1))

Title SATELLITES-DEFINITION (412.25(e)(1))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
For purposes of paragraphs (e)(2) through (e)(4) of this section, a satellite facility is a part of a hospital unit that provides inpatient services in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital.	Compliance with this requirement is determined by the FI.

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FED - C0723 - SATELLITES-NUMBER OF BEDS (412.25(e)(2))

Title SATELLITES-NUMBER OF BEDS (412.25(e)(2))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
Except as provided in paragraphs (e)(3) and (e)(5) of this section, effective for cost reporting periods beginning on or after October 1, 1999, a hospital that has a satellite facility must meet the following criteria in order to be excluded from the acute care hospital inpatient prospective payment systems for any period. In the case of a unit excluded from the prospective payment systems for the most recent cost reporting period beginning before October 1, 1997, the unit's number of State-licensed and Medicare-certified beds, including those at the satellite facility, does not exceed the unit's on the last day of the unit's last cost reporting period beginning before October 1, 1997.	Compliance with this requirement is determined by the FI.

FED - C0724 - SATELLITES-ADMISSION CRITERIA (412.25(e)(2))

Title SATELLITES-ADMISSION CRITERIA (412.25(e)(2))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
The satellite facility complies with the requirements under §412.23(b)(2).	Compliance with this requirement is determined by the FI.

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FED - C0725 - SATELLITES-INDEPENDENT STAFF (412.25(e)(2))

Title SATELLITES-INDEPENDENT STAFF (412.25(e)(2))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
The satellite facility, effective for cost reporting periods beginning on or after October 1, 2002, is not under the control of the governing body or chief executive officer of the hospital in which it is located, and it furnishes inpatient care through the use of medical personnel who are not under the control of the medical staff or chief medical officer of the hospital in which it is located.	

FED - C0726 - SATELLITES-SEPARATE RECORDS (412.25(e)(2))

Title SATELLITES-SEPARATE RECORDS (412.25(e)(2))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
The satellite facility maintains admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available.	

FED - C0727 - SATELLITES-SEPARATE BEDS (412.25(e)(2))

Title SATELLITES-SEPARATE BEDS (412.25(e)(2))

CFR 485.647(a)(2)

Type Standard

Aspen Federal Regulation Set: C 04.02 CRITICAL ACCESS HOSPITALS

Regulation Definition	Interpretive Guideline
The satellite facility has beds that are physically separate from (that is, not commingled with) the beds of the hospital in which it is located.	

FED - C0728 - SATELLITES-FISCAL INTERMEDIARY (412.25(e)(2))

Title SATELLITES-FISCAL INTERMEDIARY (412.25(e)(2))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
The satellite facility is serviced by the same fiscal intermediary as the hospital unit of which it is a part.	Compliance with this requirement is determined by the FI.

FED - C0729 - SATELLITES-COST CENTER (412.25(e)(2))

Title SATELLITES-COST CENTER (412.25(e)(2))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
The satellite facility is treated as a separate cost center of the hospital unit of which it is a part.	Compliance with this requirement is determined by the FI.

FED - C0730 - SATELLITES-MAINTAIN DATA (412.25(e)(2))

Title SATELLITES-MAINTAIN DATA (412.25(e)(2))

CFR 485.647(a)(2)

Type Standard

Aspen Federal Regulation Set: C 04.02 CRITICAL ACCESS HOSPITALS

Regulation Definition	Interpretive Guideline
The satellite facility, for cost reporting and apportionment purposes, uses an accounting system that properly allocates costs and maintains adequate statistical data to support the basis of allocation.	Compliance with this requirement is determined by the FI.

FED - C0731 - SATELLITES-FISCAL PERIOD (412.25(e)(2))

Title SATELLITES-FISCAL PERIOD (412.25(e)(2))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
The satellite facility reports its costs on the cost report of the hospital of which it is a part, covering the same fiscal period and using the same method of apportionment as the hospital of which it is a part.	Compliance with this requirement is determined by the FI.

FED - C0732 - SATELLITE FACILITIES (412.25(e)(3))

Title SATELLITE FACILITIES (412.25(e)(3))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
Except as specified in paragraph (e)(4) of this section, the provisions of paragraph (e)(2) of this section do not apply to any unit structured as a satellite facility on September 30, 1999, and excluded from the prospective payment systems on that date, to the extent the unit continues operating under the same terms and conditions, including the number of beds and square footage considered to be part of the unit, in effect on September 30, 1999.	Compliance with this requirement is determined by the FI.

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FED - C0733 - SATELLITES-RELOCATION (412.25(e)(4))

Title SATELLITES-RELOCATION (412.25(e)(4))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
In applying the provisions of paragraph (e)(3) of this section, any unit structured as a satellite facility as of September 30, 1999, may increase or decrease the square footage of the satellite facility or may decrease the number of beds in the satellite facility at any time, if these changes are made necessary by relocation of the facility to permit construction or renovation necessary for compliance with changes or local law affecting the physical facility; or because of catastrophic events such as fires, floods, earthquakes, or tornadoes.	Compliance with this requirement is determined by the FI.

FED - C0734 - SATELLITE FACILITIES (412.25(e)(5))

Title SATELLITE FACILITIES (412.25(e)(5))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
The provisions of paragraph (e)(2)(i) of this section do not apply to any inpatient rehabilitation facility that is subject to the inpatient rehabilitation facility prospective payment system under subpart P of this part, effective for cost reporting periods beginning on or after October 1, 2003.	Compliance with this requirement is determined by the FI.

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FED - C0735 - CHANGES IN CLASSIFICATION (412.25(f))

Title CHANGES IN CLASSIFICATION (412.25(f))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
For purposes of exclusions from the prospective payment system under this section, the classification of a hospital unit is effective for the unit's entire cost reporting period. Any changes in the classification of a hospital unit is made only at the start of a cost reporting period.	

FED - C0747 - NEW VS CONVERTED UNITS (412.29(a))

Title NEW VS CONVERTED UNITS (412.29(a))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
In order to be excluded from the prospective payment systems described in §412.1(a)(1) and to be paid under the prospective payment system specified in §412.1(a)(2), a rehabilitation unit must have met either the requirements for new units under §412.30(a) or converted units under §412.30(c).	Compliance with this requirement is determined by the FI.

FED - C0748 - PREADMISSION SCREENING (412.29(b))

Title PREADMISSION SCREENING (412.29(b))

CFR 485.647(a)(2)

Type Standard

Aspen Federal Regulation Set: C 04.02 CRITICAL ACCESS HOSPITALS

Regulation Definition

A rehabilitation unit must have in effect a preadmission screening procedure under which each prospective patient's condition and medical history are reviewed to determine whether the patient is likely to benefit significantly from an intensive inpatient program or assessment.

Interpretive Guideline

FED - C0749 - REHABILITATION NURSING (412.29(c))

Title REHABILITATION NURSING (412.29(c))

CFR 485.647(a)(2)

Type Standard

Regulation Definition

A rehabilitation unit must ensure that the patients receive close medical supervision and furnish, through the use of qualified personnel, rehabilitation nursing.

Interpretive Guideline

FED - C0750 - PHYSICAL & OCCUPATIONAL THERAPY (412.29(c))

Title PHYSICAL & OCCUPATIONAL THERAPY (412.29(c))

CFR 485.647(a)(2)

Type Standard

Regulation Definition

A rehabilitation unit must ensure that the patients receive close medical supervision and furnish, through the use of qualified personnel, occupational therapy.

Interpretive Guideline

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FED - C0751 - OTHER SERVICES (412.29(c))

Title OTHER SERVICES (412.29(c))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
A rehabilitation unit must ensure that the patients receive close medical supervision and furnish, through the use of qualified personnel, speech therapy, social services or psychological services, and orthotic and prosthetic services, as needed.	

FED - C0752 - PLAN OF TREATMENT (412.29(d))

Title PLAN OF TREATMENT (412.29(d))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
A rehabilitation unit must have a plan of treatment for each inpatient that is established, reviewed, and revised as needed by a physician in consultation with other professional personnel who provide services to the patient.	

FED - C0753 - MULTIDISCIPLINARY TEAM (412.29(e))

Title MULTIDISCIPLINARY TEAM (412.29(e))

CFR 485.647(a)(2)

Type Standard

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Regulation Definition

A rehabilitation unit must use a coordinated multidisciplinary team approach in the rehabilitation of each inpatient, as documented by periodic clinical entries made in the patient's medical record to note the patient's status in relationship to goal attainment.

Interpretive Guideline

FED - C0754 - TEAM CONFERENCES (412.29(e))

Title TEAM CONFERENCES (412.29(e))

CFR 485.647(a)(2)

Type Standard

Regulation Definition

A rehabilitation unit must hold team conferences at least every two weeks to determine the appropriateness of treatment.

Interpretive Guideline

FED - C0755 - DIRECTOR (412.29(f)(1))

Title DIRECTOR (412.29(f)(1))

CFR 485.647(a)(2)

Type Standard

Regulation Definition

A rehabilitation unit must have a director of rehabilitation who provides services to the unit and to its inpatients for at least 20 hours per week.

Interpretive Guideline

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FED - C0756 - DIRECTOR MD/DO (412.29(f)(2))

Title DIRECTOR MD/DO (412.29(f)(2))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
A rehabilitation unit must have a director of rehabilitation who is is a doctor of medicine or osteopathy.	

FED - C0757 - DIRECTOR-LICENSED (412.29(f)(3))

Title DIRECTOR-LICENSED (412.29(f)(3))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
A rehabilitation unit must have a director of rehabilitation who is licensed under State law to practice medicine or surgery.	

FED - C0758 - DIRECTOR-TRAINING/EXPERIENCE (412.29(f)(4))

Title DIRECTOR-TRAINING/EXPERIENCE (412.29(f)(4))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
A rehabilitation unit must have a director of rehabilitation who has had, after completing a one-year hospital internship, at least two years of training or experience in the medical management of inpatients requiring rehabilitation services.	

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FED - C0770 - DECREASE IN BEDS (412.30(a))

Title DECREASE IN BEDS (412.30(a))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
A decrease in bed capacity must remain in effect for at least a full 12-month cost reporting period before an equal or lesser number of beds can be added to the hospital's licensure and certification and considered "new" under paragraph (b) of this section.	Compliance with this requirement is determined by the FI.

FED - C0771 - DELICENSED/DECERTIFIED BEDS (412.30(a))

Title DELICENSED/DECERTIFIED BEDS (412.30(a))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
When a hospital seeks to establish a new unit under the criteria under paragraph (b) of this section, or to enlarge an existing unit under the criteria under paragraph (d) of this section, the regional office will review its records on the facility to determine whether any beds have been delicensed and decertified during the 12-month cost reporting period before the period for which the hospital seeks to add the beds. To the extent bed capacity was removed from the hospital's licensure and certification during that period, that amount of bed capacity may not be considered "new" under paragraph (b) of this section.	Compliance with this requirement is determined by the FI.

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FED - C0772 - NEW UNITS (412.30(b)(1))

Title NEW UNITS (412.30(b)(1))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
A hospital unit is considered a new unit if the hospital has not previously sought exclusion for any rehabilitation unit and has obtained approval, under State licensure and Medicare certification, for an increase in its hospital bed capacity that is greater than 50 percent of the number of beds in the unit.	Compliance with this requirement is determined by the FI.

FED - C0773 - WRITTEN CERTIFICATION (412.30(b)(2))

Title WRITTEN CERTIFICATION (412.30(b)(2))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
A hospital that seeks exclusion of a new rehabilitation unit may provide a written certification that the inpatient population the hospital intends the unit to serve meets the requirements of §412.23(b)(2) instead of showing that the unit has treated such a population during the hospital's most recent cost reporting period.	Compliance with this requirement is determined by the FI.

FED - C0774 - WRITTEN CERTIFICATION (412.30(b)(3))

Title WRITTEN CERTIFICATION (412.30(b)(3))

CFR 485.647(a)(2)

Type Standard

Aspen Federal Regulation Set: C 04.02 CRITICAL ACCESS HOSPITALS

Regulation Definition	Interpretive Guideline
The written certification described in paragraph (b)(2) of this section is effective for the first full cost reporting period during which the unit is used to provide hospital inpatient care.	Compliance with this requirement is determined by the FI.

FED - C0775 - WRITTEN CERTIFICATION (412.30(b)(4))

Title WRITTEN CERTIFICATION (412.30(b)(4))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
If a hospital that has not previously participated in the Medicare program seeks exclusion of a rehabilitation unit, it may designate certain beds as a new rehabilitation unit for the first full 12-month cost reporting period that occurs after it becomes a Medicare-participating hospital. The written certification described in paragraph (b)(2) of this section also is effective for any cost reporting period of not less than 1 month and not more than 11 months occurring between the date the hospital began participating in Medicare and the start of the hospital's regular 12-month cost reporting period.	Compliance with this requirement is determined by the FI.

FED - C0776 - CHANGE OF OWNERSHIP (412.30(b)(5))

Title CHANGE OF OWNERSHIP (412.30(b)(5))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
A hospital that has undergone a change of ownership or leasing as defined in §489.18 of this chapter is not considered	Compliance with this requirement is determined by the FI.

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to have participated previously in the Medicare program.

FED - C0777 - CONVERTED UNITS (412.30(c))

Title CONVERTED UNITS (412.30(c))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
A hospital unit is considered a converted unit if it does not qualify as a new unit under paragraph (a) of this section. A converted unit must have treated, for the hospital's most recent, consecutive, and appropriate 12-month cost reporting period (as defined by CMS or the fiscal intermediary), an inpatient population meeting the requirements of §412.23(b)(2).	Compliance with this requirement is determined by the FI.

FED - C0778 - EXPANSION OF UNITS (412.30(d)(1))

Title EXPANSION OF UNITS (412.30(d)(1))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
The beds that a hospital seeks to add to its excluded rehabilitation unit are considered new beds only if the hospital's State-licensed and Medicare-certified bed capacity increases at the start of the cost reporting period for which the hospital seeks to increase the size of its excluded rehabilitation unit, or at any time after the start of the preceding cost reporting period; and the hospital has obtained approval, under State licensure and Medicare certification, for an increase in its hospital bed capacity that is greater than 50 percent of the number of beds it seeks to add to the unit.	Compliance with this requirement is determined by the FI.

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FED - C0779 - CONVERSION OF BEDS (412.30(d)(2))

Title CONVERSION OF BEDS (412.30(d)(2))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
Bed capacity is considered to be existing bed capacity if it does not meet the definition of new bed capacity under paragraph (d)(1) of this section.	Compliance with this requirement is determined by the FI.

FED - C0780 - INCREASE IN SIZE (412.30(d)(2))

Title INCREASE IN SIZE (412.30(d)(2))

CFR 485.647(a)(2)

Type Standard

Regulation Definition	Interpretive Guideline
A hospital may increase the size of its excluded rehabilitation unit through the conversion of existing bed capacity only if it shows that, for all of the hospital's most recent, consecutive, and appropriate 12-month time period (as defined by CMS or the fiscal intermediary), the beds have been used to treat an inpatient population meeting the requirements of §412.23(b)(2).	Compliance with this requirement is determined by the FI.

FED - C0781 - RETROACTIVE ADJUSTMENTS (412.30(e))

Title RETROACTIVE ADJUSTMENTS (412.30(e))

CFR 485.647(a)(2)

Type Standard

Aspen Federal Regulation Set: C 04.02 CRITICAL ACCESS HOSPITALS

Regulation Definition	Interpretive Guideline
For cost reporting periods beginning on or after October 1, 1991, if a hospital has a new rehabilitation unit excluded from the prospective payment systems for a cost reporting period under paragraph (a) of this section or expands an existing rehabilitation unit under paragraph (c) of this section, but the inpatient population actually treated in the new unit or the beds added to the existing unit during that cost reporting period does not meet the requirements in §412.23(b)(2), CMS adjusts payments to the hospital retroactively in accordance with the provisions in §412.130 of this part.	Compliance with this requirement is determined by the FI.

FED - C2400 - COMPLIANCE WITH 489.24

Title COMPLIANCE WITH 489.24

CFR 489.20(l)

Type Standard

Regulation Definition	Interpretive Guideline
[The provider agrees,] in the case of a hospital as defined in §489.24(b), to comply with §489.24.	The term "hospital" is defined in §489.24 (b) as including critical access hospitals as defined in §1861 (mm)(1) of the Act. Therefore, a critical access hospital that operates a dedicated emergency department (as that term is defined below) is subject to the requirements of EMTALA. 42 CFR §489.20 (l) of the provider's agreement requires that hospitals comply with 42 CFR §489.24, Special responsibilities of Medicare hospitals in emergency cases. Hospitals are required to adopt and enforce a policy to ensure compliance with the requirements of §489.24. Non-compliance with EMTALA requirements will lead CMS to initiate procedures for termination from the Medicare program. Non-compliance may also trigger the imposition of civil monetary penalties by the Office of the Inspector General. Surveyors review the following documents to help determine if the hospital is in compliance with the requirement(s): o Review the bylaws, rules, and regulations of the medical staff to determine if they reflect the requirements of §489.24 and the related requirements at §489.20. o Review the emergency department policies and procedure manuals for procedures related to the requirements of §489.24 and the related requirements at §489.20.

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If a hospital violates §489.24, surveyors are to cite a corresponding violation of §489.20(l), tag C2400.

FED - C2401 - RECEIVING AN INAPPROPRIATE TRANSFER

Title RECEIVING AN INAPPROPRIATE TRANSFER

CFR 489.20(m)

Type Standard

Regulation Definition

[The provider agrees,] in the case of a hospital as defined in §489.24(b), to report to CMS or the State survey agency any time it has reason to believe it may have received an individual who has been transferred in an unstable emergency medical condition from another hospital in violation of the requirements of §489.24(e).

Interpretive Guideline

A hospital (recipient) that suspects it may have received an improperly transferred (transfer of an unstable individual with an emergency medical condition who was not provided an appropriate transfer according to §489.24(e)(2)), individual is required to promptly report the incident to CMS or the State Agency (SA) within 72 hours of the occurrence. If a recipient hospital fails to report an improper transfer, the hospital may be subject to termination of it's provider agreement according to 42 CFR§ 489.53(a).

Surveyors are to look for evidence that the recipient hospital knew, or suspected the individual had been to a hospital prior to the recipient hospital, and had not been transferred in accordance with §489.24(e). Evidence may be obtained in the medical record or through interviews with the individual, family members or staff.

Review the emergency department log and medical records of patients received as transfers. Look for evidence that:
o The hospital had agreed in advance to accept the transfers;
o The hospital had received appropriate medical records;
o All transfers had been effected through qualified personnel, transportation equipment and medically appropriate life support measures; and
o The hospital had available space and qualified personnel to treat the patients.

FED - C2402 - POSTING OF SIGNS

Title POSTING OF SIGNS

CFR 489.20(q)

Type Standard

Aspen Federal Regulation Set: C 04.02 CRITICAL ACCESS HOSPITALS

Regulation Definition

[The provider agrees,] in the case of a hospital as defined in §489.24(b), to post conspicuously in any emergency department or in a place or places likely to be noticed by all individuals entering the emergency department, as well as those individuals waiting for examination and treatment in areas other than traditional emergency departments (that is, entrance, admitting area, waiting room, treatment area) a sign (in a form specified by the Secretary) specifying the rights of individuals under section 1867 of the Act with respect to examination and treatment for emergency medical conditions and women in labor; and to post conspicuously (in a form specified by the Secretary) information indicating whether or not the hospital or rural primary care hospital (e.g., critical access hospital) participates in the Medicaid program under a State plan approved under Title XIX.

Interpretive Guideline

Section 1866(a)(1)(N)(iii) of the Social Security Act requires the posting of signs which specify the rights of individuals with EMCs and women in labor.

To comply with the requirements hospital signage must at a minimum:
o Specify the rights of individuals with EMCs and women in labor who come to the emergency department for health care services;
o Indicate whether the facility participates in the Medicaid program;
o The wording of the sign(s) must be clear and in simple terms and language(s) that are understandable by the population served by the hospital; and
o The sign(s) must be posted in a place or places likely to be noticed by all individuals entering the emergency department, as well as those individuals waiting for examination and treatment (e.g., entrance, admitting area, waiting room, treatment area).

FED - C2403 - HOSPITAL MUST MAINTAIN RECORDS

Title HOSPITAL MUST MAINTAIN RECORDS

CFR 489.20(r)(1)

Type Standard

Regulation Definition

[The provider agrees,] in the case of a hospital as defined in §489.24(b), (including both the transferring and receiving hospitals), to maintain medical and other records related to individuals transferred to or from the hospital for a period of 5 years from the date of the transfer.

Interpretive Guideline

The medical records of individuals transferred to or from the hospital must be retained in their original or legally reproduced form in hard copy, microfilm, microfiche, optical disks, computer disks, or computer memory for a period of 5 years from the date of transfer.

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FED - C2404 - ON CALL PHYSICIANS

Title ON CALL PHYSICIANS

CFR 489.20(r)(2) and 489.24(j)(1-2)

Type Standard

Regulation Definition

§489.20(r)(2)
[The hospital (including both the transferring and receiving hospitals), must maintain] a list of physicians who are on call for duty after the initial examination to provide further evaluation and/or treatment necessary to stabilize an individual with an emergency medical condition.

§489.24(j)(1)
Each hospital must maintain an on-call list of physicians on its medical staff in a manner that best meets the needs of the hospital's patients who are receiving services required under this section in accordance with the resources available to the hospital, including the availability of on-call physicians.

§489.24(j)(2)(i)
The hospital must have written policies and procedures in place to respond to situations in which a particular specialty is not available or the on-call physician cannot respond because of circumstances beyond the physician's control.

§489.24(j)(2)(ii)
The hospital must have written policies and procedures in place to provide that emergency services are available to meet the needs of patients with emergency medical conditions if it elects to permit on-call physicians to schedule elective surgery during the time that they are on call or to permit on-call physicians to have simultaneous on-call duties.

Interpretive Guideline

§489.20 (r)(2)
Section 1866 (a)(1)(iii) of the Act states, as a requirement for participation in the Medicare program, that hospitals must maintain a list of physicians who are on call for duty after the initial examination to provide treatment necessary to stabilize an individual with an EMC. The on call list identifies and ensures that the emergency department is prospectively aware of which physicians, including specialists and subspecialists are available to provide care.

A hospital can meet its responsibility to provide adequate medical personnel to meet its anticipated emergency needs by using on call physicians either to staff or to augment its emergency department, during which time the capability of its emergency department includes the services of its on call physicians.

CMS does not have requirements regarding how frequently on call physicians are expected to be available to provide on call coverage. Nor is there a pre-determined ratio CMS uses to identify how many days a hospital must provide medical staff on call coverage based on the number of physicians on staff for that particular specialty. In particular, CMS has no rule stating that whenever there are at least three physicians in a specialty, the hospital must provide 24 hour / 7 day coverage in that specialty.

Generally, in determining EMTALA compliance, CMS will consider all relevant factors, including the number of physicians on staff, other demands on these physicians, the frequency with which the hospital's patient typically require services of on call physicians, and the provisions the hospital has made for situations in which a physician in the specialty is not available or the on call physicians is unable to respond. On call coverage is a decision made by hospital administrators and the physicians who provide on call coverage for the hospital. Each hospital has the discretion to maintain the on call list in a manner that best meet the needs of the hospital's patients who are receiving services required under EMTALA in accordance with the resources available to the hospital, including the availability of on call physicians. The best practice for hospitals, which offer particular services to the public, should be available through on call coverage of the emergency department.

Physicians group names are not acceptable for identifying the on call physician. Individual physician names are to be identified on the list.

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§489.24(j)(1)
Hospitals have the ultimate responsibility for ensuring adequate on call coverage. Hospitals participating in the Medicare Program must maintain a list of physicians on call for duty after the initial examination to provide treatment necessary to stabilize an individual with an EMC. Hospitals have an EMTALA obligation to provide on call coverage for patients in need of specialized treatment if the hospital has the capacity to treat the individual.

No physician is required to be on call at all times. On call coverage should be provided for within reason depending upon the number of physicians in a specialty. A determination about whether a hospital is in compliance with these regulations must be based on the facts in each individual case. The surveyor will consider all relevant factors including the number of physicians on staff, the number of physicians in a particular specialty, other demands on these physicians, the frequency with which the hospital's patients typically require services of on call physicians, vacations, conferences, days off and the provisions the hospital has made for situations in which a physician in the specialty is not available or the on call physician is unable to respond.

If a staff physician is on call to provide emergency services or to consult with an emergency room physician in the area of his or her expertise, that physician would be considered to be available at the hospital. A determination as to whether the on call physician must physically assess the patient in the emergency department is the decision of the treating emergency physician. His or her ability and medical knowledge of managing that particular medical condition will determine whether the on call physician must come to the emergency department.

When a physician is on call for the hospital and seeing patients with scheduled appointments in his private office, it is generally not acceptable to refer emergency cases to his or her office for examination and treatment of an EMC. The physician must come to the hospital to examine the individual if requested by the treating emergency physician. If, however, if it is medically appropriate to do so, the treating emergency physician may send an individual needing the services of the on call physician to the physician's office if it is part of a hospital-owned facility (department of the hospital sharing the same Medicare provider number as the hospital) and on the hospital campus. In determining if a hospital has appropriately moved an individual from the hospital to the on call physician's office, surveyors may consider whether (1) all persons with the same medical condition are moved in such circumstances, regardless of their ability to pay for treatment; (2) there is bona fide medical reason to move the patient; and (3) appropriate medical personnel accompany the patient.

If a physician who is on call does not come to the hospital when called, but rather repeatedly or typically directs the patient to be transferred to another hospital where the physician can treat the individual, the physician may have violated EMTALA. Surveyors are to assess all facts of the case prior to making a recommendation to the RO as to

whether the physician violated EMTALA. Surveyors are to consider the individual needs and the physician circumstances, which may have an impact upon the case. Each case is to be viewed on its own merit and specific facts.

For physicians taking call simultaneously at more than one hospital, the hospitals must have policies and procedures to follow when the on call physician is not available to respond because he has been called to the other hospital to evaluate an individual. Hospital policies may include, but are not limited to procedures for back up on call physicians, or the implementation of an appropriate EMTALA transfer according to 42 CFR §489.24(e). The policies and procedures a hospital adopts to meet its EMTALA obligation is at the hospital's discretion, as long as they meet the needs of the individuals who present for emergency care taking into account the capability of the hospital and the availability of on call physicians.

The decision as to whether the on call physician responds in person or directs a non-physician practitioner (physician assistant, nurse practitioner, orthopedic tech) as his or her representative to present to the dedicated ED is made by the responsible on call physician, based on the individual's medical need and the capabilities of the hospital and applicable State scope of practice laws, hospital bylaws, and rules and regulations. The on call physician is ultimately responsible for the individual regardless of who responds to the call. In the event that the treating physician disagrees with the on-call physician's decision to send a representative and requests the appearance of the on-call physician, then both the hospital and an on-call physician who fails or refuses to appear in a reasonable period of time may be subject to sanctions for violations of the EMTALA statutory requirements.

There is no EMTALA prohibition against the treating physician consulting on a case with another physician, who may or may not be on the hospital's or CAH's on-call list, by telephone, video conferencing, transmission of test results, or any other means of communication. CMS is aware that it is increasingly common for hospitals/CAHs to use telecommunications to exchange imaging studies, laboratory results, EKG's, real-time audio and video images of patients, and/or other clinical information with a consulting physician not on the hospital/CAH premises. Such practices may contribute to improved patient safety and efficiency of care. In some cases it may be understood by the hospitals/CAHs and physicians who establish such remote consulting arrangements that the physician consultant is not available for an in-person assessment of the individual at the treating physician's hospital/CAH.

However, if a physician:
o is on a hospital's or CAH's on-call list; and
o has been requested by the treating physician to appear at the hospital; and
o fails or refuses to appear within a reasonable period of time,

then the hospital and the on-call physician may be subject to sanctions for violation of the EMTALA statutory requirements.

It is only when the treating physician requests an in-person appearance by the on-call physician that a failure by the latter to appear in person may constitute an EMTALA violation.

It is an entirely separate issue, outside the scope of EMTALA enforcement, whether or not insurers or other third party payers, including Medicare, will provide reimbursement to physicians who provide remote consultation services. Hospitals and/or physicians interested in Medicare reimbursement policy for telemedicine or telehealth services should consult Medicare Benefit Policy Manual, Pub 100-2, Chapter 18, Section §270).

Physicians that refuse to be included on a hospital's on call list but take calls selectively for patients with whom they or a colleague at the hospital have established a doctor-patient relationship while at the same time refusing to see other patients (including those individuals whose ability to pay is questionable) may violate EMTALA. If a hospital permits physicians to selectively take call while the hospital's coverage for that particular service is not adequate, the hospital would be in violation of its EMTALA obligation by encouraging disparate treatment.

If a physician on call does not fulfill his obligation to the hospital, but the hospital arranges for another staff physician in that specialty to assess the individual, and no other EMTALA requirements are violated, then the hospital may not be in violation of the regulation. However, in this circumstance, the physician who has agreed to take call and does not come to the hospital when called may have violated the regulation.

CMS allows hospitals flexibility in the utilization of their medical personnel. Allowing exemptions to medical staff members (senior physicians) would not by itself violate EMTALA.

Surveyors are to review the hospital policies or medical staff bylaws with respect to response time of the on call physician. If a physician on the list is called by the hospital to provide emergency screening or treatment and either refuses or fails to arrive within the response time established by hospital policies or medical staff bylaws, the hospital and that physician may be in violation of EMTALA. Hospitals are responsible for ensuring that on call physicians respond within a reasonable period of time. The expected response time should be stated in minutes in the hospitals policies. Terms such as "reasonable" or "prompt" are not enforceable by the hospital and therefore inappropriate in defining physician's response time. Note the time of notification and the response (or transfer) time.

§489.24(j)(2)(i)
The medical staff by-laws or policies and procedures must define the responsibility of the on call physicians to

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respond, examine and treat patients with an EMC.

Physicians, including specialists and subspecialists (e.g., neurologists) are not required to be on call at all times or required to be on call in their specialty for emergencies whenever they are visiting their own patients in the hospital. The hospital must have policies and procedures (including back-up call schedules or the implementation of an appropriate EMTALA transfer) to be followed when a particular specialty is not available or the on call physician cannot respond because of situations beyond his or her control. The hospital is ultimately responsible for providing adequate on call coverage to meet the needs of its patients.

§489.24(j)(2)(ii)
Physicians are not prohibited from performing surgery while on call. The only exception applies to Critical Access Hospital (CAH) staff. On call physicians who are reimbursed for being on call at CAHs cannot provide services at any other provider or facility. However, a hospital may have its own internal policy prohibiting elective surgery by on call physicians to better serve the needs of its patients seeking treatment for a potential emergency medical condition. When a physician has agreed to be on call at a particular hospital during a particular period of time, but has also scheduled elective surgery during that time, that physician and the hospital should have planned back-up in the event that he/she is called while performing elective surgery and is unable to respond to the situation or the implementation of an appropriate EMTALA transfer according to §489.24(e).

Physicians can be on call simultaneously at other hospitals to maximize patient access to care. When the on call physician is simultaneously on call at more than one hospital in the geographic area, all hospitals involved must be aware of the on call schedule as each hospital independently has an EMTALA obligation. The medical staff by laws or policies and procedures must define the responsibilities of the on call physicians to respond, examine and treat individuals with emergency medical conditions, and the hospital must have policies and procedures to be followed when a particular specialty is not available or the on call physician cannot respond because of situations beyond his or her control as the hospital is ultimately responsible for providing adequate on call coverage to meet the needs of its individuals.

FED - C2405 - EMERGENCY ROOM LOG

Title EMERGENCY ROOM LOG

CFR 489.20(r)(3)

Type Standard

Aspen Federal Regulation Set: C 04.02 CRITICAL ACCESS HOSPITALS

Regulation Definition

[The provider agrees,] in the case of a hospital as defined in §489.24(b) (including both the transferring and receiving hospitals), to maintain a central log on each individual who comes to the emergency department, as defined in §489.24(b), seeking assistance and whether he or she refused treatment, was refused treatment, or whether he or she was transferred, admitted and treated, stabilized and transferred, or discharged.

§489.24 The provisions of this regulation apply to all hospitals that participate in Medicare and provide emergency services.

Interpretive Guideline

The purpose of the central log is to track the care provided to each individual who comes to the hospital seeking care for an emergency medical condition.

Each hospital has the discretion to maintain the log in a form that best meets the needs of the hospital. The central log includes, directly or by reference, patient logs from other areas of the hospital that may be considered dedicated emergency departments, such as pediatrics and labor and delivery where a patient might present for emergency services or receive a medical screening examination instead of in the "traditional" emergency department. These additional logs must be available in a timely manner for surveyor review. The hospital may also keep its central log in an electronic format.

Review the emergency department log covering at least a 6 month period that contains information on all individuals coming to the emergency department and check for completeness, gaps in entries or missing information.

Hospitals with an emergency department are required under EMTALA to do the following:
o To provide an appropriate MSE to any individual who comes to the emergency department;
o Provide necessary stabilizing treatment to an individual with an EMC or an individual in labor;
o Provide for an appropriate transfer of the individual if either the individual requests the transfer or the hospital does not have the capability or capacity to provide the treatment necessary to stabilize the EMC (or the capability or capacity to admit the individual);
o Not delay examination and/or treatment in order to inquire about the individual's insurance or payment status;
o Accept appropriate transfers of individuals with emergency medical conditions if the hospital has the specialized capabilities not available at the transferring hospital and has the capacity to treat those individuals;
o Obtain or attempt to obtain written and informed refusal of examination, treatment or an appropriate transfer in the case of an individual who refuses examination, treatment or transfer; and
o Not take adverse action against a physician or qualified medical personnel who refuses to transfer an individual with an emergency medical condition, or against an employee who reports a violation of these requirements.

FED - C2406 - MEDICAL SCREENING EXAM

Title MEDICAL SCREENING EXAM

CFR 489.24(a) and 489.24(c)

Type Standard

Aspen Federal Regulation Set: C 04.02 CRITICAL ACCESS HOSPITALS

Regulation Definition	Interpretive Guideline
Applicability of provisions of this section. (1) In the case of a hospital that has an emergency department, if an individual (whether or not eligible for Medicare benefits and regardless of ability to pay) "comes to the emergency department", as defined in paragraph (b) of this section, the hospital must (i) provide an appropriate medical screening examination within the capability of the hospital's emergency department, including ancillary services routinely available to the emergency department, to determine whether or not an emergency medical condition exists. The examination must be conducted by an individual(s) who is determined qualified by hospital bylaws or rules and regulations and who meets the requirements of §482.55 of this chapter concerning emergency services personnel and direction; and (b) If an emergency medical condition is determined to exist, provide any necessary stabilizing treatment, as defined in paragraph (d) of this section, or an appropriate transfer as defined in paragraph (e) of this section. If the hospital admits the individual as an inpatient for further treatment, the hospital's obligation under this section ends, as specified in paragraph (d)(2) of this section. (2) Nonapplicability of provisions of this section. Sanctions under this section for inappropriate transfer during a national emergency or for the direction or relocation of an individual to receive medical screening at an alternate location do not apply to a hospital with a dedicated emergency department located in an emergency area, as specified in section 1135(g)(1) of the Act. A waiver of these sanctions is limited to a 72-hour period beginning upon the implementation of a hospital disaster protocol, except that, if a public health emergency involves a pandemic infectious disease (such as pandemic influenza), the waiver will continue in effect until the termination of the applicable declaration of a	§489.24(a) A "hospital with an emergency department" is defined in §489.24(b) as a hospital with a dedicated emergency department. An EMTALA obligation is triggered for such a hospital when an individual comes by him or herself, with another person, to a hospital's dedicated emergency department (as that term is defined above) and a request is made by the individual or on the individual's behalf, or a prudent layperson observer would conclude from the individual's appearance or behavior a need, for examination or treatment of a medical condition. In such a case, the hospital has incurred an obligation to provide an appropriate medical screening examination for the individual and stabilizing treatment or an appropriate transfer. The purpose of the medical screening examination is to determine whether or not an emergency medical condition exits. If an individual who is not a hospital patient comes elsewhere on hospital property (that is, the individual comes to the hospital but not to the dedicated emergency department), an EMTALA obligation on the part of the hospital may be triggered if either the individual requests examination or treatment for an emergency medical condition or if a prudent layperson observer would believe that the individual is suffering from an emergency medical condition. The term "hospital property" means the entire main hospital campus as defined in §413.65(a), including the parking lot, sidewalk and driveway or hospital departments, including any building owned by the hospital that are within 250 yards of the hospital. If an individual is registered as an outpatient of the hospital and they present on hospital property but not to a dedicated emergency department, the hospital does not incur an obligation to provide a medical screening examinations for that individual if they have begun to receive a scheduled course of outpatient care. Such an individual is protected by the hospital conditions of participation that protect patient's health and safety and to ensure that quality care is furnished to all patients in Medicare-participating hospital. If such an individual experiences an EMC while receiving outpatient care, the hospital does not have an obligation to conduct an MSE for that patient. As discussed in greater detail below, such a patient has adequate protections under the Medicare COPs and state law. If an individual is initially screened in a department or facility on-campus outside of the ED, the individual could be moved to another hospital department or facility on-campus to receive further screening or stabilizing treatment without such movement being regarded as a transfer, as long as (1) all persons with the same medical condition are moved in such circumstances, regardless of their ability to pay for treatment; (2) there is bona fide medical reason to move the individual; and (3) appropriate medical personnel accompany the individual. The same is also true for an individual who presents to the dedicated emergency department (e.g., patient with an eye injury in need of stationary ophthalmology equipment located in the eye clinic) and must be moved to another hospital-owned facility or department on-campus for further screening or stabilizing treatment. The movement of the individual between hospital departments is not considered an EMTALA transfer under this section, since the individual is simply being

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public health emergency, as provided for by section 1135(e)(1)(B) of the Act.

(c) Use of Dedicated Emergency Department for Nonemergency Services
If an individual comes to a hospital's dedicated emergency department and a request is made on his or her behalf for examination or treatment for a medical condition, but the nature of the request makes it clear that the medical condition is not of an emergency nature, the hospital is required only to perform such screening as would be appropriate for any individual presenting in that manner, to determine that the individual does not have an emergency medical condition.

moved from one department of a hospital to another department or facility of the same hospital.

Hospitals should not move individuals to off-campus facilities or departments (such as an urgent care center or satellite clinic) for a MSE. If a individual comes to a hospital-owned facility or department, which is off-campus and operates under the hospital's Medicare provider number, §1867 (42 C.F.R. §489.24) will not apply to that facility and/or department unless it meets the definition of a dedicated emergency department.

If, however, such a facility does not meet the definition of a dedicated ED, it must screen and stabilize the patient to the best of its ability or execute an appropriate transfer if necessary to another hospital or to the hospital on whose Medicare provider number it is operated. Hospital resources and staff available at the main campus are likewise available to individuals seeking care at the off campus facilities or departments within the capability of the hospital. Movement of the individual to the main campus of the hospital is not considered a transfer since the individual is simply being moved from one department of a hospital to another department or facility of the same hospital. In addition, a transfer from such an entity (i.e., an off-campus facility that meets the definition of a dedicated ED) to a nonaffiliated hospital (i.e., a hospital that does not own the off-campus facility) is allowed where the facility at which the individual presented cannot stabilize the individual and the benefits of transfer exceed the risks of transfer. In other words, there is no requirement under EMTALA that the individual be always transferred back to the hospital that owns and operates the off-campus dedicated ED. Rather, the requirement of EMTALA is that the individual be transferred to an appropriate facility for treatment.

If a request were made for emergency care in a hospital department off the hospital's main campus that does not meet the definition of a dedicated emergency department, EMTALA would not apply. However, such an off-campus facility must have policies and procedures in place as how to handle patients in need of immediate care. For example, the off-campus facility policy may direct the staff to contact the emergency medical services/911 (EMS) to take the patient to an emergency department (not necessarily the emergency department of the hospital that operates the off-campus department, but rather the closest emergency department) or provide the necessary care if it is within the hospital's capability. Therefore, a hospital off-campus facility that does not meet the definition of a dedicated emergency department does not have an EMTALA obligation and not required to be staffed to handle potential EMC.

Medicare hospitals that do not provide emergency services must meet the standard of §482.12 (f), which requires hospitals to have written policies and procedures for the appraisal of emergencies, initial treatment within its capability and capacity, and makes an appropriate referral to a hospital that is capable of providing the necessary emergency services.

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If a hospital has an EMTALA obligation, it must screen individuals to determine if an EMC exists. It is not appropriate to merely "log in" an individual and not provide a MSE. An MSE is the process required to reach, with reasonable clinical confidence, the point at which it can be determined whether the individual has an EMC or not. An MSE is not an isolated event. It is an ongoing process that begins, but typically does not end, with triage.

Triage entails the clinical assessment of the individual's presenting signs and symptoms at the time of arrival at the hospital, in order to prioritize when the individual will be seen by a physician or other qualified medical personnel (QMP)

Individuals coming to the emergency department must be provided a MSE appropriate to the individuals' presenting signs and symptoms, as well as the capability and capacity of the hospital. Depending on the individual's presenting signs and symptoms, an appropriate MSE can involve a wide spectrum of actions ranging from a simple process involving only a brief history and physical examination to a complex process that also involves performing ancillary studies and procedures such as (but not limited to) lumbar punctures, clinical laboratory tests, CT scans, and/or other diagnostic tests and procedures. The medical record must reflect continued monitoring according to the individual's needs until it is determined whether or not the individual has an EMC and, if he/she does, until he/she is stabilized or appropriately transferred. There should be evidence of this ongoing monitoring prior to discharge or transfer.

The MSE must be the same MSE that the hospital would perform on any individual coming to the hospital's dedicated emergency department with those signs and symptoms, regardless of the individual's ability to pay for medical care. If a hospital applies in a nondiscriminatory manner (i.e. a different level of care must not exist based on payment status, race, national origin, etc.) a screening process that is reasonably calculated to determine whether an EMC exists, it has met its obligations under the EMTALA. If the MSE is appropriate and does not reveal an EMC, the hospital has no further obligation under 42 CFR §489.24.

Regardless of a positive or negative individual outcome, a hospital would be in violation of the anti-dumping statute if it fails to meet any of the medical screening requirements under 42 CFR §489.24. The clinical outcome of an individual's condition is not a proper basis for determining whether an appropriate screening was provided or whether a person transferred was stable. However, the outcome may be a "red flag" indicating that a more thorough investigation is needed. Do not make decisions base on clinical information that was not available at the time of stabilizing or transfer. If an individual was misdiagnosed, but the hospital utilized all of its resources, a violation of the screening requirement did not occur.

It is not impermissible under EMTALA for a hospital to follow normal registration procedures for individuals who come to the emergency department. For example, a hospital may ask the individual for an insurance card, so long as

doing so does not delay the medical screening examination. In addition, the hospital may seek other information (not payment) from the individual's health plan about the individual such as medical history. And, in the case of an individual with an emergency medical condition, once the hospital has conducted the medical screening examination and has initiated stabilizing treatment, it may seek authorization for all services from the plan, again, as long as doing so does not delay the implementation of the required MSE and stabilizing treatment.

A hospital that is not in a managed care plan's network of designated providers cannot refuse to screen and treat (or appropriately transfer, if the medical benefits of the transfer outweigh the risks or if the individual requests the transfer) individuals who are enrolled in the plan who come to the hospital if that hospital participates in the Medicare program.

Once an individual has presented to the hospital seeking emergency care, the determination of whether an EMC exists is made by the examining physician(s) or other qualified medical personnel of the hospital.

Medicare participating hospitals that provide emergency services must provide a medical screening examination to any individual regardless of diagnosis (e.g., labor, AIDS), financial status (e.g., uninsured, Medicaid), race, and color, national origin (e.g. Hispanic or Native American surnames), and/or disability, etc.

A hospital, regardless of size or patient mix, must provide screening and stabilizing treatment within the scope of its abilities, as needed, to the individuals with emergency medical conditions who come to the hospital for examination and treatment.

"Labor" is defined to mean the process of childbirth beginning with the latent or early phase of labor and continuing through the delivery of the placenta. A woman experiencing contractions is in true labor, unless a physician , certified nurse-midwife, or other qualified medical person acting within his or her scope of practice as defined in hospital medical staff bylaws and State law, certifies that, after a reasonable time of observation, the woman is in false labor.

An infant that is born alive is a "person" and an "individual" under 1 U.S.C. 8(a) and the screening requirement of EMTALA applies to "any individual" who comes to the emergency department. If an infant was born alive in a dedicated emergency department, and a request was made on that infant's behalf for screening for a medical condition, (or if a prudent layperson would conclude, based on the infant's appearance or behavior, that the infant needed examination or treatment for a (medical condition) the hospital and physician could be liable for violating EMTALA for failure to provide such a medical screening examination.

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If an infant is born alive elsewhere on the hospital's campus (i.e., not in the hospital's dedicated emergency department) and a prudent layperson observer would conclude, based on the born-alive infant's appearance or behavior, that the infant was suffering from an emergency medical condition, the hospital and its medical staff are required to perform a medical screening examination on the infant to determine whether or not an emergency medical condition exists. Whether in the DED or elsewhere on the hospital's campus, if the physician or other authorized qualified medical personnel performing the medical screening examination determines that the infant is suffering from an emergency medical condition, the hospital has an obligation under EMTALA to provide stabilizing treatment or an appropriate transfer. If the hospital admits the infant, its obligation under EMTALA ends.

A minor (child) can request an examination or treatment for an EMC. The hospital is required by law to conduct the examination if requested by an individual or on the individual's behalf to determine if an EMC exists. Hospital personnel should not delay the MSE by waiting for parental consent. If after screening the minor, it is determined than no EMC is present, the staff can wait for parental consent before proceeding with further examination and treatment.

On-campus provider-based entities (such as rural health clinics or physician offices) are not subject to EMTALA, therefore it would be inappropriate to move individuals to these facilities for a MSE or stabilizing treatment under this Act.

If an individual is not on hospital property (which includes a hospital owned and operated ambulance), this regulation is not applicable. Hospital property includes ambulances owned and operated by the hospital, even if the ambulance is not on the hospital campus. An individual in a non-hospital owned ambulance, which is on hospital property is considered to have come to the hospital's emergency department. An individual in a non- hospital owned ambulance not on the hospital's property is not considered to have come to the hospital's emergency department when the ambulance personnel contact "Hospital A" by telephone or telemetry communications. If an individual is in an ambulance, regardless of whether the ambulance is owned by the hospital, a hospital may divert individuals when it is in "diversionary" status because it does not have the staff or facilities to accept any additional emergency patients at that time. However, if the ambulance is owned by the hospital, the diversion of the ambulance is only appropriate if the hospital is being diverted pursuant to community-wide EMS protocols. Moreover, if any ambulance (regardless of whether or not owned by the hospital) disregards the hospital's instructions and brings the individual on to hospital campus, the individual has come to the hospital and the hospital has incurred an obligation to conduct a medical screening examination for the individual.

Hospitals that deliberately delay moving an individual from an EMS stretcher to an emergency department bed do not thereby delay the point in time at which their EMTALA obligation begins. Furthermore, such a practice of "parking" patients arriving via EMS, refusing to release EMS equipment or personnel, jeopardizes patient health and adversely

impacts the ability of the EMS personnel to provide emergency response services to the rest of the community. Hospitals that " park " patients may also find themselves in violation of 42 CFR 482.55, the Hospital Condition of Participation for Emergency Services, which requires that hospitals meet the emergency needs of patients in accordance with acceptable standards of practice.

On the other hand, this does not mean that a hospital will necessarily have violated EMTALA and/or the hospital CoPs if it does not, in every instance, immediately assume from the EMS provider all responsibility for the individual, regardless of any other circumstances in the ED. For example, there, may be situations when a hospital does not have the capacity or capability at the time of the individual's presentation to provide an immediate medical screening examination (MSE) and, if needed, stabilizing treatment or an appropriate transfer. So, if the EMS provider brought an individual to the dedicated ED at a time when ED staff was occupied dealing with multiple major trauma cases, it could under those circumstances be reasonable for the hospital to ask the EMS provider to stay with the individual until such time as there were ED staff available to provide care to that individual. However, even if a hospital cannot immediately complete an appropriate MSE, it must still assess the individual's condition upon arrival to ensure that the individual is appropriately prioritized, based on his/her presenting signs and symptoms, to be seen by a physician or other QMP for completion of MSE. The hospital should also assess whether the EMS provider can appropriately monitor the individual's condition..

Should a hospital, which is not in diversionary status, fail to accept a telephone or radio request for transfer or admission, the refusal could represent a violation of other Federal or State requirements (e.g., Hill-Burton). If you suspect a violation of related laws, refer the case to the responsible agency for investigation.

The following two circumstances will not trigger EMTALA:
o The use of a hospital's helipad by local ambulance services or other hospitals for the transport of individuals to tertiary hospitals located throughout the State does not trigger an EMTALA obligation for the hospital that has the helipad on its property when the helipad is being used for the purpose of transit as long as the sending hospital conducted the MSE prior to transporting the individual to the helipad for medical helicopter transport to a designated recipient hospital. The sending hospital is responsible for conducting the MSE prior to transfer to determine if an EMC exists and implementing stabilizing treatment or conducting an appropriate transfer. Therefore, if the helipad serves simply as a point of transit for individuals who have received a MSE performed prior to transfer to the helipad, the hospital with the helipad is not obligated to perform another MSE prior to the individual's continued travel to the recipient hospital. If, however, while at the helipad, the individual's condition deteriorates, the hospital at which the helipad is located must provide another MSE and stabilizing treatment within its capacity if requested by medical personnel accompanying the individual.

o If as part of the EMS protocol, EMS activates helicopter evacuation of an individual with a potential EMC, the hospital that has the helipad does not have an EMTALA obligation if they are not the recipient hospital, unless a request is made by EMS personnel, the individual or a legally responsible person acting on the individual's behalf for the examination or treatment of an EMC.

Hospitals are not relieved of their EMTALA obligation to screen, provide stabilizing treatment and or an appropriate transfer to individuals because of prearranged community or State plans that have designated specific hospitals to care for selected individuals (e.g., Medicaid patients, psychiatric patients, pregnant women). Hospitals located in those States which have State/local laws that require particular individuals, such as psychiatric or indigent individuals, to be evaluated and treated at designated facilities/hospitals may violate EMTALA if the hospital disregards the EMTALA requirements and does not conduct an MSE and provide stabilizing treatment or conduct an appropriate transfer prior to referring the individual to the State/local facility. If, after conducting the MSE and ruling out an EMC (or after stabilizing the EMC) the sending hospital needs to transfer an individual to another hospital for treatment, it may elect to transfer the individual to the hospital so designated by these State or local laws. Hospitals are also prohibited from discharging individuals who have not been screened or who have an emergency medical condition to non-hospital facilities for purposes of compliance with State law. The existence of a State law requiring transfer of certain individuals to certain facilities is not a defense to an EMTALA violation for failure to provide an MSE or failure to stabilize an EMC therefore hospitals must meet the federal EMTALA requirements or risk violating EMTALA.

If a screening examination reveals an EMC and the individual is told to wait for treatment, but the individual leaves the hospital, the hospital did not "dump" the individual unless:
o The individual left the emergency department based on a "suggestion" by the hospital;
o The individual's condition was an emergency, but the hospital was operating beyond its capacity and did not attempt to transfer the individual to another facility, or
o If a individual leaves a hospital Against Medical Advice (AMA) or LWBS, on his or her own free will (no coercion or suggestion) the hospital is not in violation of EMTALA.

Hospital resources and staff available to inpatients at the hospital for emergency services must likewise be available to individuals coming to the hospital for examination and treatment of an EMC because these resources are within the capability of the hospital. For example, a woman in labor who presents at a hospital providing obstetrical services must be treated with the resources available whether or not the hospital normally provides unassigned emergency obstetrical services.

The MSE must be conducted by an individual(s) who is determined qualified by hospital by-laws or rules and

regulations and who meets the requirements of §482.55 concerning emergency services personnel and direction. The designation of the qualified medical personnel (QMP) should be set forth in a document approved by the governing body of the hospital. If the rules and regulations of the hospital are approved by the board of trustees or other governing body, those personnel qualified to perform the medical screening examinations may be set forth in the rules and regulations, or the hospital by-laws. It is not acceptable for the hospital to allow informal personnel appointments that could frequently change.

Refer to Tag C2407 for stabilizing treatment and inpatients and Tag C2409 for an appropriate transfer for EMTALA.

EMTALA does not apply to hospital inpatients. The existing hospital CoPs protect individuals who are already patients of a hospital and who experience an EMC. Hospitals that fail to provide treatment to these patients may be subject to further enforcement actions.

If the surveyor discovers during the investigation that a hospital did not admit an individual in good faith with the intention of providing treatment (i.e., the hospital used the inpatient admission as a means to avoid EMTALA requirements), then the hospital is considered liable under EMTALA and actions may be pursued.

§489.24 (a)(2)
Pursuant to section 1135(b) of the Social Security Act (Act), under certain emergency circumstances EMTALA sanctions may be waived. Specifically, waivers of sanctions are permitted with respect to:
o The inappropriate transfer of an individual who has not been stabilized. Pursuant to the Act the inappropriate transfer must arise out of the circumstances of the emergency; or
o The direction or relocation of an individual to receive a medical screening examination (MSE) at an alternate location pursuant to an appropriate State emergency preparedness plan or State pandemic preparedness plan. If a State emergency preparedness plan or pandemic preparedness plans has been activated in the emergency area, then the direction or relocation of individuals for MSEs is considered to be pursuant to a state plan.

Section 1135(g)(1) of the Act defines "emergency area" as a geographical area in which there exists:
o An emergency or disaster declared by the President pursuant to the National Emergencies Act or the Robert T. Stafford Disaster Relief and Emergency Assistance Act; and
o A public health emergency declared by the Secretary pursuant to section 319 of the Public Heath Service Act.

The waiver of sanction applies only to hospitals:
o With dedicated emergency departments; and
o Located in an emergency area during an emergency period; and

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o When the Secretary has exercised his waiver authority pursuant to section 1135 of the Act..

In addition, the Act and the regulations at §489.24(a)(2) limit the duration of the waiver from EMTALA enforcement to 72 hours in most cases. The 72- hour period begins with the implementation of a hospital disaster protocol. In the case of an infectious pandemic disease, however, the waiver continues past the 72 hours and remains in effect until termination of the declaration of a public health emergency as described in section 1135(e)(1)(B) of the Act.

When all of the above conditions exist, then the Regional Office (RO) may issue an advisory notice that hospitals with dedicated emergency departments in the emergency area will not, during the emergency period, be subject to EMTALA sanctions for:
o Redirecting individuals seeking an MSE when a State emergency preparedness plan or a pandemic preparedness plan has been activated in the emergency area; or
o Inappropriate transfers arising out of the circumstances of the emergency.

The RO notice will also indicate that the waiver of sanctions will be for the 72-hour period starting with each hospital's activation of its hospital disaster protocol. However, the 72- hour period may not in any case start before the effective date of the Secretary ' s public health emergency declaration. In the case of an infectious pandemic disease, however, the RO notice will indicate that the waiver may continue past the 72-hour period and remain in effect until termination of the declaration of public health emergency as described in section 1135(e)(1)(B) of the Act.

EMTALA complaints alleging violations by a hospital in an emergency area during an emergency period related to failure to provide an MSE or an inappropriate transfer must first be reviewed by the RO to determine whether a waiver of sanctions was in effect. The review may require some preliminary investigation, usually by telephone. If the review indicates a waiver was in effect for that hospital at the time of the complaint, then the RO will not authorize the State Agency to conduct an EMTALA investigation of the complaint.

§489.24(c)
Any individual with a medical condition that presents to a hospital's ED must receive an MSE that is appropriate for their medical condition. The objective of the MSE is to determine whether or not an emergency medical condition exists. This does not mean that all EMTALA screenings must be equally extensive. If the nature of the individual's request makes clear that the medical condition is not of an emergency nature, the MSE is reflective of the individual presenting complaints or symptoms. A hospital may, if it chooses, have protocols that permit a QMP (e.g., registered nurse) to conduct specific MSE(s) if the nature of the individual's request for examination and treatment is within the scope of practice of the QMP (e.g., a request for a blood pressure check and that check reveals hat the patient's blood pressure is within normal range). Once the individual is screened and it is determined the individual has only

presented to the ED for a non-emergency purpose, the hospital's EMTALA obligation ends for that individual at the completion of the MSE. Hospitals are not obligated under EMTALA to provide screening services beyond those needed to determine that there is no EMC.

For a hospital to be exempted from its EMTALA obligations to screen individuals presenting at its emergency department for non-emergency tests (e.g., individual has consulted with physician by telephone and the physician refers the individual to a hospital emergency department for a non-emergency test) the hospital must be able to document that it is only being asked to collect evidence, not analyze the test results, or to otherwise examine or treat the individual. Furthermore, a hospital may be exempted from its EMTALA obligations to screen individuals presenting to its dedicated emergency department if the individual had a previously scheduled appointment.

If an individual presents to an ED and requests pharmaceutical services (medication) for a medical condition, the hospital generally would have an EMTALA obligation. Surveyors are encouraged to ask probing questions of the hospital staff to determine if the hospital in fact had an EMTALA obligation in this situation (e.g., did the individual present to the ED with an EMC and informed staff they had not taken their medication? Was it obvious from the nature of the medication requested that it was likely that the patient had an EMC?). The circumstances surrounding why the request is being made would confirm if the hospital in fact has an EMTALA obligation. If the individual requires the medication to resolve or provide stabilizing treatment of an EMC, then the hospital has an EMTALA obligation. Hospitals are not required by EMTALA to provide medication to individuals who do not have an EMC simply because the individual is unable to pay or does not wish to purchase the medication from a retail pharmacy or did not plan appropriately to secure prescription refills.

If an individual presents to a dedicated emergency department and requests services that are not for a medical condition, such as preventive care services (immunizations, allergy shots, flu shots) or the gathering of evidence for criminal law cases (e.g., sexual assault, blood alcohol test), the hospital is not obligated to provide a MSE under EMTALA to this individual.

Attention to detail concerning blood alcohol testing (BAT) in the ED is instrumental when determining if a MSE is to be conducted. If an individual is brought to the ED and law enforcement personnel request that emergency department personnel draw blood for a BAT only and does not request examination or treatment for a medical condition, such as intoxication and a prudent lay person observer would not believe that the individual needed such examination or treatment, then the EMTALA's screening requirement is not applicable to this situation because the only request made on behalf of the individual was for evidence. However, if for example, the individual in police custody was involved in a motor vehicle accident or may have sustained injury to him or herself and presents to the ED, a MSE would be warranted to determine if an EMC exists.

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When law enforcement officials request hospital emergency personnel to provide clearance for incarceration, the hospital has an EMTALA obligation to provide a MSE to determine if an EMC exists. If no EMC is present, the hospital has met its EMTALA obligation and no further actions are necessary for EMTALA compliance.

Surveyors will evaluate each case on its own merit when determining a hospital's EMTALA obligation when law enforcement officials request screening or BAT for use as evidence in criminal proceedings.

This principle also applies to sexual assault cases.

FED - C2407 - STABILIZING TREATMENT

Title STABILIZING TREATMENT

CFR 489.24(d)(1-3)

Type Standard

Regulation Definition	Interpretive Guideline
(1) General. Subject to the provisions of paragraph (d)(2) of this section, if any individual (whether or not eligible for Medicare benefits) comes to a hospital and the hospital determines that the individual has an emergency medical condition, the hospital must provide either- (i) within the capabilities of the staff and facilities available at the hospital, for further medical examination and treatment as required to stabilize the medical condition. (ii) For for transfer of the individual to another medical facility in accordance with paragraph (e) of this section.	§489.24(d)(1)(i) A hospital is obligated to provide the services specified in the statute and this regulation regardless of whether a hospital will be paid. After the medical screening has been implemented and the hospital has determined that an emergency medical condition exists, the hospital must provide stabilizing treatment within its capability and capacity. Capabilities of a medical facility mean that there is physical space, equipment, supplies, and specialized services that the hospital provides (e.g., surgery, psychiatry, obstetrics, intensive care, pediatrics, trauma care). Capabilities of the staff of a facility means the level of care that the personnel of the hospital can provide within the training and scope of their professional licenses. This includes coverage available through the hospitals on call roster.
(2) Exception: Application to inpatients. (i) If a hospital has screened an individual under paragraph (a) of this section and found the individual to have an emergency medical condition, and admits that individual as an inpatient in good faith in order to stabilize the emergency medical condition, the hospital has satisfied its special responsibilities under this section with respect to that individual (ii) This section is not applicable to an inpatient who was	The capacity to render care is not reflected simply by the number of persons occupying a specialized unit, the number of staff on duty, or the amount of equipment on the hospital's premises. Capacity includes whatever a hospital customarily does to accommodate patients in excess of its occupancy limits §489.24 (b). If a hospital has customarily accommodated patients in excess of its occupancy limits by whatever mean (e.g., moving patients to other units, calling in additional staff, borrowing equipment from other facilities) it has, in fact, demonstrated the ability to provide services to patients in excess of its occupancy limits. A hospital may appropriately transfer (see Tag C2409) an individual before the sending hospital has used and

admitted for elective (nonemergency) diagnosis or treatment.
(iii) A hospital is required by the conditions of participation for hospitals under Part 482 of this chapter to provide care to its inpatients in accordance with those conditions of participation.

(3) Refusal to consent to treatment.
A hospital meets the requirements of paragraph (d)(1)(i) of this section with respect to an individual if the hospital offers the individual the further medical examination and treatment described in that paragraph and informs the individual (or a person acting on the individual's behalf) of the risks and benefits to the individual of the examination and treatment, but the individual (or a person acting on the individual's behalf) does not consent to the examination or treatment. The medical record must contain a description of the examination, treatment, or both if applicable, that was refused by or on behalf of the individual. The hospital must take all reasonable steps to secure the individual's written informed refusal (or that of the person acting on his or her behalf). The written document should indicate that the person has been informed of the risks and benefits of the examination or treatment, or both.

exhausted all of its resources available if the individual requests the transfer to another hospital for his or her treatment and refuses treatment at the sending hospital.

To comply with the MSE and stabilization requirements of §1867 all individuals with similar medical conditions are to be treated consistently. Compliance with local, State, or regionally approved EMS transport of individuals with an emergency is usually deemed to indicate compliance with §1867; however a copy of the protocol should be obtained and reviewed at the time of the survey.

If community wide plans exist for specific hospitals to treat certain EMCs (e.g., psychiatric, trauma, physical or sexual abuse), the hospital must meet its EMTALA obligations (screen, stabilize, and or appropriately transfer) prior to transferring the individual to the community plan hospital. An example of a community wide plan would be a trauma system hospital. A trauma system is a comprehensive system providing injury prevention services and timely and appropriate delivery of emergency medical treatment for people with acute illness and traumatic injury. These systems are designed so that patients with catastrophic injuries will have the quickest possible access to an established trauma center or a hospital that has the capabilities to provide comprehensive emergency medical care. These systems ensure that the severely injured patient can be rapidly cared for in the facility that is most appropriately prepared to treat the severity of injury.

Community plans are designed to provide an organized, pre-planned response to patient needs to assure the best patient care and efficient use of limited health care resources. Community plans are designed to augment physician's care if the necessary services are not within the capability of the hospital but does not mandate patient care nor transfer patterns. Patient health status frequently depends on the appropriate use of the community plans. The matching of the appropriate facility with the needs of the patient is the focal point of this plan and assures every patient receives the best care possible. Therefore, a sending hospital's appropriate transfer of an individual in accordance with community wide protocols in instances where it cannot provide stabilizing treatment would be deemed to indicate compliance with §1867.

If an individual seeking care is a member of a managed health care plan (e.g., HMO, PPO or CMP), the hospital is obligated to comply with the requirements of §489.24 regardless of the individual's payor source or financial status. The hospitals is obligated to provide the services necessary to determine if an EMC is present and provide stabilizing treatment if indicated. This is true regardless if the individual is enrolled in a managed care plan that restricts its enrollees' choice of health care provider. EMTALA is a requirement imposed on hospitals, and the fact that an individual who comes to the hospital is enrolled in a managed care plan that does not contract with that hospital has no bearing on the obligation of the hospital to conduct an MSE and to at lease initiate stabilizing treatment. A managed health care plan may only state the services for which it will pay or decline payment, but that does not

excuse the hospital from compliance with EMTALA.

42 CFR §489.24 (b) defines stabilized to mean
" ... that no material deterioration of the condition is likely, within reasonable medical probability, to result from, or occur during, the transfer of the individual from a facility, or with respect to an "emergency medical condition" as defined in this section under paragraph (1) of that definition, that a woman has delivered the child and the placenta."

The regulation sets the standard determining when a patient is stabilized.

If a hospital is unable to stabilize an individual within its capability, an appropriate transfer should be implemented. To be considered stable the emergency medical condition that caused the individual to seek care in the dedicated ED must be resolved, although the underlying medical condition may persist. For example, an individual presents to a hospital complaining of chest tightness, wheezing, and shortness of breath and has a medical history of asthma. The physician completes a medical screening examination and diagnoses the individual as having an asthma attack that is an emergency medical condition. Stabilizing treatment is provided (medication and oxygen) to alleviate the acute respiratory symptoms. In this scenario the EMC was resolved and the hospital's EMTALA obligation is therefore ended, but the underlying medical condition of asthma still exists. After stabilizing the individual, the hospital no longer has an EMTALA obligation. The physician may discharge the individual home, admit him/her to the hospital, or transfer (the "appropriate transfer" requirement under EMTALA does not apply to this situation since the individual has been stabilized) the individual to another hospital depending on his/her needs. The preceding example does not reflect a change in policy, rather it is a clarification as to when an appropriate transfer is to be implemented to decrease hospitals risk of being in violation of EMTALA due to inappropriate transfers.

An individual will be deemed stabilized if the treating physician or QMP attending to the individual in the emergency department/hospital has determined, within reasonable clinical confidence, that the emergency medical condition has been resolved.

For those individuals whose EMCs have been resolved the physician or QMP has several options:
o Discharge home with follow-up instructions. An individual is considered stable and ready for discharge when, within reasonable clinical confidence, it is determined that the individual has reached the point where his/her continued care, including diagnostic work-up and/or treatment, could be reasonably performed as an outpatient or later as an inpatient, provided the individual is given a plan for appropriate follow-up care as part of the discharge instructions. The EMC that caused the individual to present to the dedicated ED must be resolved, but the underlying medical condition may persist. Hospitals are expected within reason to assist/provide discharged individuals the necessary information to secure the necessary follow-up care to prevent relapse or worsening of the medical condition

upon release from the hospital; or
o Inpatient admission for continued care.

Hospitals are responsible for treating and stabilizing, within their capacity and capability, any individual who presents him/herself to a hospital with an EMC. The hospital must provide care until the condition ceases to be an emergency or until the individual is properly transferred to another facility. An inappropriate transfer or discharge of an individual with an EMC would be a violation of EMTALA.

If a hospital is alleged to have violated EMTALA by transferring an unstable individual without implementing an appropriate transfer according to §489.24(e), and the hospital believes that the individual was stable (EMC resolved) the burden of proof is the responsibility of the transferring hospital. When interpreting the facts the surveyor should assess whether or not the individual was stable. Was it reasonable to believe that the transferring hospital should have been knowledgeable of the potential complications during transport? To determine whether the individual was stable and treated appropriately surveyors will request that the QIO physician review the case.

If the treating physician is in doubt that an individual's EMC is stabilized the physician should implement an appropriate transfer (see Tag C2409) to prevent a potential violation of EMTALA, if his/her hospital cannot provide further stabilizing treatment.

If a physician is not physically present at the time of transfer, then the qualified medical personnel (as determined by hospital bylaws or other board-approved documents) must consult with a physician to determine if an individual with an EMC is to be transferred to another facility for further stabilizing treatment.

The failure of a receiving facility to provide the care it maintained it could provide to the individual when the transfer was arranged should not be construed to mean that the individual's condition worsened as a result of the transfer.

In the case of psychiatric emergencies, if an individual expressing suicidal or homicidal thoughts or gestures, if determined dangerous to self or others, would be considered to have an EMC.

Psychiatric patients are considered stable when they are protected and prevented from injuring or harming him/herself or others. The administration of chemical or physical restraints for purposes of transferring an individual from one facility to another may stabilize a psychiatric patient for a period of time and remove the immediate EMC but the underlying medical condition may persist and if not treated for longevity the patient may experience exacerbation of the EMC. Therefore, practitioners should use great care when determining if the medical condition is in fact stable after administering chemical or physical restraints.

A hospital's EMTALA obligation ends when a physician or qualified medical person has made a decision:
o That no emergency medical condition exists (even though the underlying medical condition may persist);
o That an emergency medical condition exists and the individual is appropriately transferred to another facility; or
o That an emergency medical condition exists and the individual is admitted to the hospital for further stabilizing treatment.

§489.24(d)(1)(ii)
When a hospital has exhausted all of its capabilities in attempting to resolve the EMC, it must effect an appropriate transfer of the individual (see Tag C2409).

42 CFR §489.24 (b) defines transfer to mean
" ... the movement (including the discharge) of an individual outside a hospital's facilities at the direction of any person employed by (or affiliated or associated, directly or indirectly, with) the hospital, but does not include such a movement of an individual who has been declared dead or leaves the facility without the permission of any such person. If discharge would result in the reasonable medical probability of material deterioration of the patient, the emergency medical condition should not be considered to have been stabilized."

If an individual is admitted as an inpatient, EMCs must be stabilized either by the hospital to which an individual presents or the hospital to which the individual is transferred. If a woman is in labor, the hospital must deliver the baby and the placenta or transfer appropriately. She may not be transferred unless she, or a legally responsible person acting on her behalf, requests a transfer and a physician or other qualified medical personnel, in consultation with a physician, certifies that the benefits to the woman and/or the unborn child outweigh the risks associated with the transfer.

If the individual's condition requires immediate medical stabilizing treatment and the hospital is not able to attend to that individual because the emergency department is operating beyond its capacity, then the hospital should transfer the individual to a hospital that has the capability and capacity to treat the individual's EMC.

§489.24(d)(2)(i)
A hospital's EMTALA obligation ends when the individual has been admitted in good faith for inpatient hospital services whether or not the individual has been stabilized. An individual is considered to be "admitted" when the decision is made to admit the individual to receive inpatient hospital services with the expectation that the patient will remain in the hospital at least overnight. Typically, we would expect that this would be documented in the patient's chart and medical record at the time that a physician signed and dated the admission order. Hospital policies should

clearly delineate, which practitioners are responsible for writing admission orders.

A hospital continues to have a responsibility to meet the patient emergency needs in accordance with hospital CoPs at 42 CFR Part 482. The hospital CoPs protect individuals who are admitted, and they do not permit the hospital to inappropriately discharge or transfer any patient to another facility. The hospital CoPs that are most relevant in this case are as follows: emergency services, governing body, discharge planning, quality assurance and medical staff.

Hospitals are responsible for assuring that inpatients receive acceptable medical care upon admission. Hospital services for inpatients should include diagnostic services and therapeutic services for medical diagnosis, treatment, and care of the injured, disabled or sick persons with the intention of treating patients.

If during an EMTALA investigation there is a question as to whether an individual was admitted so that a hospital could avoid its EMTALA obligation, the SA surveyor is to consult with RO personnel to determine if the survey should be expanded to a survey of the hospital CoPs. After completion of the survey, the case is to be forwarded to the RO for violation determination. If it is determined that the hospital admitted the individual solely for the purpose of avoiding its EMTALA obligation, then the hospital is liable under EMTALA and may be subject to further enforcement action.

§489.24(d)(2)(i)
Individuals admitted to the hospital for elective medical services are not protected by EMTALA. The hospital CoPs protect all classifications of inpatients, elective and emergent.

§489.24(d)(2)(ii)
If an inpatient develops an EMC, the hospital is required to meet the patient's emergency needs in accordance with acceptable standards of practice. The hospital CoPs protects patients who are admitted, and the hospital may not discharge or transfer any patient to another facility inappropriately. The protective CoPs are found at 42 C.F.R. Part 482. The five CoPs that are most relevant in affording patients protection in cases when patients with an EMC is admitted are as follows:
o Emergency services (§482.55)
o Governing body (§482.12)
o Discharge planning (§482.43)
o Quality assessment and performance improvement (§482.21)
o Medical staff (§482.22)
If a hospital is noncompliant with any of the above COPs, the hospital will be subject to enforcement action.

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§489.24(d)(3)
The medical record should reflect that screening, further examination, and or treatment were offered by the hospital prior to the individual's refusal.

In the event an individual refuses to consent to further examination or treatment, the hospital must indicate in writing the risks/benefits of the examination and/or treatment; the reasons for refusal; a description of the examination or treatment that was refused; and the steps taken to try to secure the written, informed refusal if it was not secured.

Hospitals may not attempt to coerce individuals into making judgments against their interest by informing them that they will have to pay for their care if they remain but that their care will be free or at a lower cost if they transfer to another hospital.

An individual may only refuse examination, treatment, or transfer on behalf of a patient if the patient is incapable of making an informed choice for him/herself.

FED - C2408 - DELAY IN EXAMINATION OR TREATMENT

Title DELAY IN EXAMINATION OR TREATMENT

CFR 489.24(d)(4-5)

Type Standard

Regulation Definition	Interpretive Guideline
(4) Delay in treatment. (i) A participating hospital may not delay providing an appropriate medical screening examination required under paragraph (a) of this section or further medical examination and treatment required under paragraph (d)(1) of this section in order to inquire about the individual's method of payment or insurance status. (ii)A participating hospital may not seek, or direct an individual to seek, authorization from the individual's insurance company for screening or stabilization services to be furnished by a hospital, physician, or nonphysician practitioner to an individual until after the hospital has provided the appropriate medical screening examination	§489.24:(d)(4)(i),(ii),(iii)and (iv) Hospitals should not delay providing a medical screening examination or necessary stabilizing treatment by inquiring about an individual's ability to pay for care. All individuals who present to a hospital and request an MSE for a medical condition (or have a request for an MSE made on their behalf) must receive that screening examination, regardless of the answers the individual may give to the insurance questions asked during the registration process. In addition, a hospital may not delay screening or treatment to any individual while it verifies the information provided. Hospitals may follow reasonable registration processes for individuals presenting with an EMC. Reasonable registration processes may include asking whether an individual is insured and, if so, what the insurance is, as long as this inquiry do not delay screening, treatment or unduly discourage individuals from remaining for further evaluation. The registration process permitted in the dedicated ED typically consists of collecting demographic information, insurance information, whom to contact in an emergency and other relevant information. If a managed care member comes to a hospital that offers emergency services, the hospital must provide the services

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required under paragraph (a) of this section, and initiated any further medical examination and treatment that may be required to stabilize the emergency medical condition under paragraph (d)(1) of this section.

(iii) An emergency physician or nonphysician practitioner is not precluded from contacting the individual's physician at any time to seek advice regarding the individual's medical history and needs that may be relevant to the medical treatment and screening of the patient, as long as this consultation does not inappropriately delay services required under paragraph (a) or paragraphs (d)(1) and (d)(2) of this section.

Hospitals may follow reasonable registration processes for individuals for whom examination or treatment is required by this section, including asking whether an individual is insured and, if so, what that insurance is, as long as that inquiry does not delay screening or treatment. Reasonable registration processes may not unduly discourage individuals from remaining for further evaluation.

A hospital meets the requirements of paragraph (d)(1)(ii) of this section with respect to an individual if the hospital offers to transfer the individual to another medical facility in accordance with paragraph (e) of this section and informs the individual (or a person acting on his or her behalf) of the risks and benefits to the individual of the transfer, but the individual (or a person acting on the individual's behalf) does not consent to the transfer. The hospital must take all reasonable steps to secure the individual's written informed refusal (or that of a person acting on his or her behalf). The written document must indicate the person has been informed of the risks and benefits of the transfer and state the reasons for the individual's refusal. The medical record must contain a description of the proposed transfer that was refused by or on behalf of the individual.

required under the EMTALA statute without regard for the individual's insurance status or any prior authorization requirement of such insurance.

This requirement applies equally to both the referring and the receiving (recipient) hospital. Therefore, it may be a violation if the receiving hospital delays acceptance of the transfer of an individual with an unstabilized EMC pending receipt or verification of financial information. It would not be a violation if the receiving hospital delayed acceptance of the transfer of an individual with a stabilized EMC pending receipt or verification of financial information because EMTALA protections no longer apply once a patient is stabilized.

If a delay in screening was due to an unusual internal crisis whereby it was simply not within the capability of the hospital to provide an appropriate screening examination at the time the individual came to the hospital (e.g., mass casualty occupying all the hospital's resources for a time period), surveyors are to interview hospital staff members to elicit the facts surrounding the circumstances to help determine if there was a violation of EMTALA.

§489.24(d)(5)
For individuals who refuse to consent to a transfer, the hospital staff must inform the individual of the risks and benefits and document the refusal and, if possible, place a signed informed consent to refusal of the transfer in the individual's medical record.

If an individual or the individual's representative refuses to be transferred and also refuses to sign a statement to that effect, the hospital may document such refusals as they see fit.

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FED - C2409 - APPROPRIATE TRANSFER

Title APPROPRIATE TRANSFER

CFR 489.24(e)(1-2)

Type Standard

Regulation Definition

(1) General
If an individual at a hospital has an emergency medical condition that has not been stabilized (as defined in paragraph (b) of this section), the hospital may not transfer the individual unless -
(i) The transfer is an appropriate transfer (within the meaning of paragraph (e)(2) of this section); and
(ii)(A) The individual (or a legally responsible person acting on the individual's behalf) requests the transfer, after being informed of the hospital's obligations under this section and of the risk of transfer.
The request must be in writing and indicate the reasons for the request as well as indicate that he or she is aware of the risks and benefits of the transfer.

(B) A physician (within the meaning of section 1861(r)(1) of the Act) has signed a certification that, based upon the information available at the time of transfer, the medical benefits reasonably expected from the provision of appropriate medical treatment at another medical facility outweigh the increased risks to the individual or, in the case of a woman in labor, to the woman or the unborn child, from being transferred. The certification must contain a summary of the risks and benefits upon which it is based; or

(C) If a physician is not physically present in the emergency department at the time an individual is transferred, a qualified medical person (as determined by the hospital in its bylaws or

Interpretive Guideline

§489.24 (e)(1)(i)
If an individual's EMC has not been resolved prior to transferring the individual to another hospital the sending hospital has an EMTALA obligation, and must meet the four requirements of an "appropriate" transfer. These requirements are found in §489(e)(2):
o §489.24(2)(i), the transferring hospital provides medical treatment within its capacity that minimizes the risks to the individual's health and, in the case of a woman in labor, the health of the unborn child;
o §489.24(e)(2)(ii), the receiving facility has agreed to accept the patient, has space and qualified personnel available for the treatment;
o §489.24(e)(2)(iii), the transferring hospital sends to the receiving facility all medical records related to the emergency medical condition which are available at the time of transfer and;
o §489.24(e)(2)(iv), the transfer is effected through qualified personnel and transportation equipment.

§489.24 (e)(1)(ii)(A) and (B)
Section 1861 (r)(i) of the Act defines physicians as:
A doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action. (This provision is not to be construed to limit the authority of a doctor or medicine or osteopathy to delegate tasks to other qualified health care personnel to the extent recognized under State law or a State's regulatory mechanism).

The regulation at §489.24 (e)(1) requires an express written certification. Physician certification cannot simply be implied from the findings in the medical record and the fact that the patient was transferred.

The certification must state the reason(s) for transfer. The narrative rationale need not be a lengthy discussion of the individual's medical condition reiterating facts already contained in the medical record, but it should give a complete picture of the benefits to be expected from appropriate care at the receiving (recipient) facility and the risks associated with the transfer, including the time away from an acute care setting necessary to effect the transfer. The risks and benefits certification should be specific to the condition of the patient upon transfer.

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rules and regulations) has signed a certification described in paragraph (e)(1)(ii)(B) of this section after a physician (as defined in section 1861(r)(1) of the Act) in consultation with the qualified medical person, agrees with the certification and subsequently countersigns the certification. The certification must contain a summary of the risks and benefits upon which it is based.

(2) A transfer to another medical facility will be appropriate only in those cases in which -
(i) The transferring hospital provides medical treatment within its capacity that minimizes the risks to the individual's health and, in the case of a woman in labor, the health of the unborn child;
(ii) The receiving facility
(A) Has available space and qualified personnel for the treatment of the individual; and
(B) Has agreed to accept transfer of the individual and to provide appropriate medical treatment.

(iii) The transferring hospital sends to the receiving facility all medical records (or copies thereof) related to the emergency condition which the individual has presented that are available at the time of the transfer, including available history, records related to the individual's emergency medical condition, observations of signs or symptoms, preliminary diagnosis, results of diagnostic studies or telephone reports of the studies, treatment provided, results of any tests and the informed written consent or certification (or copy thereof) required under paragraph (e)(1)(ii) of this section, and the name and address of any on-call physician (described in paragraph (g) of this section) who has refused or failed to appear within a reasonable time to provide necessary stabilizing treatment. Other records (e.g., test results not yet available or historical records not readily available from the

This rationale may be on the certification form or in the medical record. In cases where the individual's medical record does not include a certification, give the hospital the opportunity to retrieve the certification. Certifications may not be backdated. Document the hospital's response.

Women in Labor
o Regardless of practices within a State, a woman in labor may be transferred only if she or her representative requests the transfer and if a physician or other qualified medical personnel signs a certification that the benefits outweigh the risks. If the hospital does not provide obstetrical services, the benefits of a transfer may outweigh the risks. A hospital cannot cite State law or practice as the basis for transfer.
o Hospitals that are not capable of handling high-risk deliveries or high-risk infants often have written transfer agreements with facilities capable of handling high-risk cases. The hospital must still meet the screening, treatment, and transfer requirements.

The certification that the benefits reasonably expected from the provision of appropriate medical treatment at another medical facility outweigh the risk of the transfer is not required for transfers of individuals who no longer have an emergency medical condition.

The date and time of the physician certification should closely match the date and time of the transfer.

§489.24 (e)(1)(ii)(C)
A QMP may sign the certification of benefits versus risks of a transfer only after consultation with the physician who authorizes the transfer. If a QMP determines that the transfer to another facility is in the best interest of the individual and signs the certification of benefits versus risks, a physician's countersignature must be obtained within the established timeframe according to hospital policies and procedures.

§489.24 (e)(2)(i)
This is the first requirement of an appropriate transfer.

The provision of treatment to minimize the risks of transfer is merely one of the four requirements of an appropriate transfer. If the patient requires treatment, it must be sufficient to minimize the risk likely to occur or result from the transfer.

Note: The four requirements of an "appropriate" transfer are applied only if the transfer is to another medical facility. In other words, the hospital has the alternative of either (1) providing treatment to stabilize the emergency medical condition and subsequently admitting, discharging or transferring the individual, or (2) appropriately transferring an

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hospital's files) must be sent as soon as practicable after transfer; and

(iv) The transfer is effected through qualified personnel and transportation equipment, as required, including the use of necessary and medically appropriate life support measures during the transfer.

unstabilized individual to another medical facility if the emergency medical condition still exists. There is no "third" option of simply "referring" the individual away after performing step one (treatment to minimize the risk of transfer) of the four transfer requirements of an appropriate transfer.

If an individual is moved to another part of the hospital, the transfer requirements are not applicable because technically the patient has not been transferred.

If an individual is moved to a diagnostic facility located at another hospital with the intention of returning to the first hospital, an appropriate transfer (within the meaning of paragraph (e)(2) of this subsection) must still be effectuated. It is reasonable to expect the recipient hospital with the diagnostic capability to communicate (e.g., telephonic report or documentation within the medical record) with the transferring hospital its findings of the medical condition and a status report of the individual during and after the procedure. Implementing an appropriate transfer back to the sending hospital is not necessary.

Surveyor Probes
After the investigation of the transferring hospital, call or go to the receiving (recipient) facility and determine whether the receiving (recipient) facility verifies the transferring hospital's information. In cases of discrepancy, obtain the medical record from the transferring and receiving hospitals and the ambulance service for review. Review each hospital's information. If you determine that it is necessary to conduct a complaint investigation at the receiving (recipient) hospital, notify the RO to request an extension of the investigation timeframe.

Review the transfer logs for the entire hospital, not merely the emergency department. Examine the following for appropriate transfers:
o Transfers to off-site testing facilities and return;
o Death or significant adverse outcomes;
o Refusals of examination, treatment, or transfer;
o Patients leaving against medical advice (AMA);
o Returns to the emergency department within 48 hours; and
o Emergency department visits where the individual is logged in for an unreasonable amount of time before the time indicated for commencement of the medical screening examination.

§489.24 (e)(2)(A) and (B)
This is the second requirement of an appropriate transfer.

The transferring hospital must obtain permission from the receiving (recipient) hospital to transfer an individual. The

transferring hospital should document its communication with the receiving (recipient) hospital, including the date and time of the transfer request and the name of the person accepting the transfer.

§489.24 (e)(2)(iii)
This is the third requirement of an appropriate transfer.

Necessary medical records must accompany individuals being transferred to another hospital. If a transfer is in an individual's best interest, it should not be delayed until records are retrieved or test results come back from the laboratory. Whatever medical records are available at the time the individual is transferred should be sent to the receiving (recipient) hospital with the patient. Test results that become available after the individual is transferred should be telephoned to the receiving (recipient) hospital, and then mailed or sent via electronic transmission consistent with HIPAA provisions on the transmission of electronic data.

Surveyor Probe
Documentation in the medical records should identify the services that were performed before transfer.

§489.24 (e)(2)(iv)
This is the fourth requirement of an appropriate transfer.

Emergency medical technicians may not always be "qualified personnel" for purposes of transferring an individual under these regulations. Depending on the individual's condition, there may be situations in which a physician's presence or some other specialist's presence might be necessary. The physician at the sending hospital (and not the receiving hospital) has the responsibility to determine the appropriate mode, equipment, and attendants for transfer.

While the sending hospital is ultimately responsible for ensuring that the transfer is effected appropriately, the hospital may meet its obligations as it sees fit. These regulations do not require that a hospital operate an emergency medical transportation service.

FED - C2410 - WHISTLEBLOWER PROTECTION

Title WHISTLEBLOWER PROTECTION

CFR 489.24(e)(3)

Type Standard

Aspen Federal Regulation Set: C 04.02 CRITICAL ACCESS HOSPITALS

Regulation Definition	Interpretive Guideline
A participating hospital may not penalize or take adverse action against a physician or a qualified medical person described in paragraph (e)(1)(ii)(C) of this section because the physician or qualified medical person refuses to authorize the transfer of an individual with an emergency medical condition that has not been stabilized, or against any hospital employee because the employee reports a violation of a requirement of this section.	A "participating hospital" means a hospital that has entered into a provider agreement under §1866 of the Act. Hospital employees reporting alleged EMTALA violations are also protected by this regulation.

FED - C2411 - RECIPIENT HOSPITAL RESPONSIBILITIES

Title RECIPIENT HOSPITAL RESPONSIBILITIES

CFR 489.24(f)

Type Standard

Regulation Definition	Interpretive Guideline
A participating hospital that has specialized capabilities or facilities (including, but not limited to, facilities such as burn units, shock-trauma units, neonatal intensive care units, or (with respect to rural areas) regional referral centers, which, for purposes of this subpart, means hospitals meeting the requirements of referral centers found at §412.96 of this chapter) may not refuse to accept from a referring hospital within the boundaries of the United States an appropriate transfer of an individual who requires such specialized capabilities or facilities if the receiving hospital has the capacity to treat the individual. This requirement applies to any participating hospital with specialized capabilities, regardless of whether the hospital has a dedicated emergency department.	A participating hospital that has specialized capabilities or facilities may not refuse to accept from a referring hospital an appropriate transfer of an individual who requires such specialized capabilities or facilities. This assumes that, in addition to its specialized capabilities the recipient hospital has the capacity to treat the individual, and that the transferring hospital lacks that capability or capacity. This requirement applies to any participating hospital with specialized capabilities, regardless of whether the hospital has a dedicated emergency department. See Tag C2409 for discussion of an appropriate transfer. A hospital with specialized capabilities or facilities includes, but is not limited to, facilities such as burn units, shock-trauma units, or neonatal intensive care units. With respect to rural areas, this includes regional referral centers which meet the requirements of referral centers found at 42 CFR §412.96. A hospital with specialized capabilities or facilities that has the necessary capacity to treat an individual with an emergency medical condition may not condition, or attempt to condition, its acceptance of an appropriate transfer of an individual on the use by the sending hospital of a particular transport service instead of the transport arrangements made by the attending physician at the sending hospital. A hospital with specialized capabilities that delays the treatment of an individual who arrives as a transfer from

another facility could be in violation of EMTALA, depending on the circumstances. Hospitals that deliberately delay moving an individual from an EMS stretcher do not thereby delay the point in time at which their EMTALA obligation begins. Furthermore, such a practice of "parking" patients arriving via EMS, refusing to release EMS equipment or personnel, jeopardizes patient health and adversely impacts the ability of the EMS personnel to provide emergency response services to the rest of the community. On the other hand, this does not mean that a hospital will necessarily have violated EMTALA and /or the hospital CoPs if it does not, in every instance, immediately assume from the EMS provider all responsibility for the individual, regardless of any other circumstances in the hospital.

Lateral transfer, that is, transfers between facilities of comparable resources, are not mandated by §489.24(e), because the benefits of such transfer would not be likely to outweigh the risks, except where the sending hospital has a serious capacity problem, a mechanical failure of equipment, or similar situations.

The number of patients that may be occupying a specialized unit, the number of staff on duty, or the amount of equipment on the hospital's premises do not in and of themselves reflect the capacity of the sending or recipient hospital to care for additional patients. If a hospital generally has accommodated additional patients by whatever means (e.g., moving patients to other units, calling in additional staff, borrowing equipment from other facilities), it has demonstrated the ability to provide services to patients in excess of its occupancy limit. For example, a hospital may be able to care for one or more severe burn patients without opening up a "burn unit." In this example, if the recipient hospital has the capacity, the hospital would have a duty to accept an appropriate transfer of an individual requiring the hospital's capabilities, providing the sending hospital lacked the specialized services to treat the individual. The provisions of this requirement are applicable only when the sending hospital is located within the boundaries of the United States. Medicare participating hospitals with specialized capabilities or facilities are not obligated to accept transfers from hospitals located outside of the boundaries of the United States.

When investigating an allegation that a hospital has violated the EMTALA recipient hospital responsibility requirements, it is usually necessary to also obtain a copy of the patient's medical record from the transferring facility.

Rural Regional Referral Centers
The criteria for classifying hospitals as rural regional referral centers are defined in 42 CFR §412.96 for the purpose of exemptions and adjustments of payment amounts under the Inpatient Prospective Payment System. The criteria in 42 CFR §412.96 are applicable to the nondiscrimination provisions of §489.24. Check with the appropriate CMS RO for information as to whether the hospital is designated as a rural regional referral center. A designated rural regional referral center is obligated to accept appropriate transfers of individuals who require the hospital's specialized capabilities if the hospital has the capacity to treat the individual.

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FED - C9999 - FINAL OBSERVATIONS

Title FINAL OBSERVATIONS

CFR

Type Memo Tag

Regulation Definition **Interpretive Guideline**